

**CONFLICT OF INTEREST, PROTECTION OF PUBLIC
OWNERSHIP, IN DRUG DEVELOPMENT DEALS
BETWEEN TAX-EXEMPT, FEDERALLY SUPPORTED
LABS AND THE PHARMACEUTICAL INDUSTRY
PART 1**

Y 4. SM 1:103-5

Conflict of Interest, Protection of... **ING**

BEFORE THE
SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES, AND TECHNOLOGY
OF THE
COMMITTEE ON SMALL BUSINESS
HOUSE OF REPRESENTATIVES

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

WASHINGTON, DC, MARCH 11, 1993

Printed for the use of the Committee on Small Business

Serial No. 103-5



SEP 24 1993

U.S. GOVERNMENT PRINTING OFFICE

WASHINGTON : 1993

66-049±

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402

ISBN 0-16-041281-1

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DRUG DEVELOPMENT COLLABORATION BETWEEN NON-PROFIT FEDERAL SUPPORTED RESEARCH LABS AND DRUG MANUFACTURERS: WHO OWNS THE RESULTS? HOW SHOULD THEY BE PRICED?

THURSDAY, MARCH 11, 1993

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES, AND TECHNOLOGY,
COMMITTEE ON SMALL BUSINESS,
Washington, DC.

The subcommittee met, pursuant to notice, at 9:38 a.m., in room 2359-A, Rayburn House Office Building, Hon. Ron Wyden, (chairman of the subcommittee) presiding.

Chairman WYDEN. The subcommittee will come to order. Today, the Subcommittee on Regulation, Business Opportunities, and Technology continues its 2-year-long inquiry into the pricing of drugs and medical devices which is the result of cooperation between taxpayer-supported, nonprofit, research laboratories and the pharmaceutical industry.

The potential importance to the Nation's public health of this medical research collaboration is not in dispute. From these projects flow life-enhancing treatments for cancer, medications for cardiovascular disease, and cures for diseases and conditions that formerly meant death or a lifetime of disability for many of our fellow citizens.

But this collaboration over time also has cemented the economic foundation of a very large, very profitable industry. On a continuing and increasing basis, the pharmaceutical industry mines a mother lode of valuable medical discoveries from a laboratory system that Federal taxpayers support with almost \$10 billion per year. Of this \$10 billion, \$3 dollars of every \$4 go to a university or independent lab.

The Federal administrators who supervise this system appear to have little control over the prices charged by private drug manufacturers, who are their partners in either project-specific or broad-based research ventures. This system results in the commercialization of drugs discovered and developed in Federal laboratories, then priced out of sight by the pharmaceutical industry.

Today, the subcommittee turns to the experience of private, nonprofit research labs, some in universities, some independent, receiving significant, if not a majority, of their annual operating budget

through Federal grants. In 1991, for example, the top 25 independent and university labs received over \$5 billion in Federal awards, mostly through NIH grants.

Of special interest to the subcommittee are the instances where private nonprofit research institutes, receiving the bulk of their financial support from the Federal Government, sign exclusive technology transfer agreements with private drug companies. Such agreements, by definition, can be extremely detrimental to small business because they create monopolies dominated by very large multinational pharmaceutical corporations that reduce marketplace competition in our country.

As a case study, the subcommittee intends to use a major 10-year-long agreement, entered into by the Sandoz Corp. of Basel, Switzerland, and the Scripps Research Institute of La Jolla, CA. Scripps gets most of its operating funds, almost \$100 million per year, from the Federal taxpayer.

It has signed an exclusive technology transfer agreement with Sandoz, which will supersede an already existing exclusive arrangement between Scripps and Johnson & Johnson Corp. As a result of the agreement, Sandoz will have access to approximately \$1 billion worth of federally supported research.

A billion dollars is obviously a lot of taxpayer money. One would hope that the Government would scrutinize how it was being spent. But in this case, the key Government agency was neither informed nor consulted about the deal. We have a situation where the labs and the drug companies have been romancing each other, cutting sweetheart agreements, and jilting the taxpayer.

Here is one for Ripley. This apparently is standard operating procedure.

The Scripps-Sandoz deal raises many troubling questions. First, are some federally supported research institutions under no legal obligation to even show the Government the agreements that they have entered into with private drug companies?

Second, is the Federal Government bolstering the profit margin of a large foreign corporation? Competition is frozen in the United States, decreasing market access for small companies, and probably encouraging higher drug prices for our consumers.

In addition, it appears that the Federal Government has turned a blind eye toward conflict of interest risks involving key administrators or researchers at these tax exempt, federally subsidized institutions. Drug companies may reward these individuals with consulting contracts and equity ownership incentives. Clearly, these sweetheart deals can bias decisions made by these key lab personnel in two respects; First, the research direction taken by the federally subsidized labs, and second, who gets to market the results.

However, in response to pressure from the drug industry, both the Department of Health and Human Services and the previous administration squelched conflict of interest regulations intended to discourage misuse of Federal grants, resulting in an atmosphere of troubling entrepreneurship among insiders at these labs. This is unacceptable.

Because of our concern with potential conflicts of interest, the subcommittee will examine evidence that a key administrator at Scripps has a lucrative consulting contract with Sandoz, the drug

manufacturer who enjoys an exclusive technology transfer agreement with the laboratory.

The subcommittee will look at whether this arrangement influences research decisions at the lab? Whether the public interest is protected?

For the record, Johnson & Johnson Corp. and the Sandoz Corp. have both been invited to attend the subcommittee's hearing. They have declined the subcommittee's invitation to testify, although both have submitted written statements to the hearing record at the subcommittee's request. Without objection, those statements will be included in the record.

[The statements may be found in the appendix.]

Chairman WYDEN. The Chair notes that the National Institutes of Health, at the subcommittee's request, is looking beyond the Scripps-Sandoz and Scripps-Johnson & Johnson deals. The National Institutes of Health is trying to define the extent of similar arrangements throughout its grantee community. Moreover, NIH is surveying more than a hundred research institutions receiving NIH money.

Dr. Bernadine Healy, the National Institutes of Health director, will testify today on the progress of her inquiry, and the specifics of the Scripps-Sandoz and Scripps-Johnson & Johnson collaborations.

Beyond the question of pricing of products, these deals raise many issues which are of critical concern to scientists, the Government, taxpayers, and small business.

How will this deal affect normal interchange between scientists within and outside of Scripps, and how will it affect the course of ground breaking science? Will a Scripps scientist whose bread is not only buttered but paid for by Sandoz be barred from speaking to colleagues at the University of Oregon, or at Georgetown?

What kinds of controls exist to prevent an unscrupulous administrator from selling access to the lab for what amounts to a professional or financial gain?

In addition, do our drug companies have the same kind of access to public-supported labs in foreign countries that foreign companies appear to have to ours?

In the Chair's view, Government acquiescence to arguments by federally supported research institutions that drug company collaboration deals should remain secret would be irresponsible in the extreme. Continued refusal to share this information ought to be grounds for divorce, and certainly the withholding of Federal grant funds.

Finally, the Chair notes that there are substantial questions as to whether the Scripps deals comply with the Bayh-Dole Act, which is the principal Federal technology transfer law.

The Chair will take special interest in this issue, and intends to examine specifically the impact of these deals on small business, and the encouragement of monopolistic pricing practices on important new drugs.

[Chairman Wyden's statement may be found in the appendix.]

Chairman WYDEN. The Chair would also like to note that there is absolutely nothing partisan about the issue of promoting technology transfer among small business, ensuring that the tax funds are

well spent, and protecting our consumers against price gouging. That is not the way that this subcommittee does its business.

We are pleased to welcome our new ranking minority member, the gentleman from Texas, Mr. Combest, and recognize him for his opening statement at this time.

Mr. COMBEST. Thank you much, Mr. Chairman. I appreciate your kind remarks.

Mr. Chairman, I want to first say that I look forward to working with you in a bipartisan manner on the many real problems facing the Nation's 20 million small businesses.

I believe that there are serious policy questions that need to be addressed, many of which you addressed in your opening remarks, in connection with collaborative biomedical research agreements between private research institutions and their industrial partners.

However, I also have some concerns as to why the subcommittee is focusing on only two players in this area. Hundreds of such agreements have existed since Congress enacted the Bayh-Dole Act of 1980.

Because of past requests from the subcommittee, the National Institutes of Health has asked 103 universities and private research institutions for all information that may have been collected about institutions receiving significant Federal funding.

I am concerned that by focusing on only one agreement, the Sandoz-Scripps agreement, that there is an appearance of an impropriety which may not exist.

Furthermore, Mr. Chairman, it is my understanding that NIH has received little or no response from the many institutions contacted. While NIH has received some information on the agreement between Scripps and Sandoz, my understanding is that few others who are scheduled to testify here today have seen the agreement in question. I also understand that this agreement has not been completely finalized, and would not go into effect for years.

Mr. Chairman, the biotechnology field is one of the many shining stars in our economy. Some folks at this hearing may try to contradict that, but the facts are clear. NIH's own estimate claims that by the year 2000 that \$50 billion in revenues and thousands of new jobs can be attributed to the biotechnology field.

While I understand the need to address possible policy concerns, I hope that the subcommittee will move prudently.

Finally, Mr. Chairman, as you know, Sandoz Pharmaceutical Corp. was unable to testify this morning. Consequently, Sandoz has provided me with a written statement, together with their March 5 letter, which I hereby request be included in the hearing record.

Chairman WYDEN. Without objection, so ordered.

Mr. COMBEST. Thank you, Mr. Chairman.

[Mr. Combest's statement and the referenced materials may be found in the appendix.]

Chairman WYDEN. I thank my colleague, and look forward to working with him on these issues.

Let me recognize the gentleman from Nevada, Mr. Bilbray.

Mr. BILBRAY. Mr. Chairman, I would like to thank you for having this hearing. After reading a lot of the testimony and what has been going on, I think that it is a shock to me as it is to the taxpayer what has been happening in this area. It is my hope that these

hearings will bring up some questions and find some solutions to this problem.

I have a full statement, but I would like to have it entered into the record in its entirety.

I would also like to say to Dr. Healy, that she is going to be sorely missed. She has done a great job over at the National Institutes of Health.

Chairman WYDEN. I thank my colleague. Your statement will be entered into the record in its entirety.

[Mr. Bilbray's statement may be found in the appendix.]

Chairman WYDEN. We want to welcome our new colleague, Mr. Torkildsen, our new Member from Massachusetts, and we look forward to his participation.

Mr. TORKILDSEN. Thank you, Mr. Chairman. I do want to thank Dr. Healy for her work, and the witnesses today.

This is a key area. As a new Member of Congress, I just appreciate the chance that we are going to have a public hearing on it. There is much to be explored. As my ranking member, Mr. Combest said, perhaps not many people really have read these agreements. I guess that the best thing that can happen is a more thorough public knowledge of them.

I do want to thank the chairman for calling this hearing. I do not want this to look like we are just looking at one agreement. But if we can explore the whole nature of these agreements, I think that everyone would benefit from understanding them better.

Chairman WYDEN. I thank my colleague. Gentlemen.

Mr. SISISKY. No comment.

Chairman WYDEN. No comment.

Mr. TUCKER, our new colleague from California.

Mr. TUCKER. Mr. Chairman, thank you very much for the opportunity to participate in this hearing. I, too, want to join in applauding your initiative to bring this issue to the fore. To the ranking member, good morning, also.

Mr. Chairman, I believe that this is a very good beginning at looking at these agreements. I look forward to working with you and the rest of the committee on this matter.

Chairman WYDEN. I thank my colleague for his cooperation. We are very pleased to have him as a new member on our committee as well, and know that he is going to be making a very extensive contribution in the work that we do.

Let me continue to recognize our colleagues. Another new Member of Congress, Mr. Dickey from Arkansas.

Mr. DICKEY. No comment.

Chairman WYDEN. Mr. Kim of California.

Mr. KIM. Thank you, Mr. Chairman, for inviting me today. This is my first hearing and first meeting that I have ever attended.

Mr. Chairman, I am a bit disappointed today that our first hearing is not focused on the general issue of the health of small business. American small businesses are hurting right now, and they need our help right now.

Mr. Chairman, this is the Subcommittee on Regulation, Business Opportunities, and Technology. I have just come from the private sector where I have been all of my life running small businesses. I was constantly faced with the more and more conflicting Federal

regulations that have become obstacles to growth and new job creation.

I wanted to do something about that, so I am here as a Congressman. I am looking forward to focusing on the impact of Federal regulations on small businesses. I think that should be the number one priority of this subcommittee.

President Clinton has proposed a major economic stimulus package with specific emphasis on helping small businesses. His package is on the fast track in Congress.

Mr. Chairman, we should be holding hearings focusing on small business opportunities, and examining whether or not there are other actions that could be taken to improve business and economic growth.

I think that there are many. The reforming of regulations is one of them. I think this subcommittee is best suited to pursue this agenda. I think that we should be doing that today. No offense to anyone here, especially the distinguished witness, the Director of NIH. But I do not see the issue of joint private-Federal pharmaceuticals as a sufficiently significant problem facing America's small business community today, and warranting this urgent hearing.

Are there any small business witnesses in the three panels before us? There does not appear to be.

Mr. Chairman, there are many new freshmen in Congress and, in particular, on this subcommittee. We did not come here to support business as usual. We came here to get the job done.

I believe that this subcommittee should concentrate on the number one issue of regulation and business opportunities, as they affect the average small business, not special interests.

I do not think that this is the best way to get started. I hope that our next hearing will reflect the top priorities of the American small business community.

Mr. Chairman, I look forward to working with you. Thank you for yielding.

Chairman WYDEN. I thank my colleague.

The gentleman from California.

Mr. HUFFINGTON. Mr. Chairman, good morning. I will make my comments brief in the interest of time.

The subject matter of the hearing that you have convened is interesting, Mr. Chairman. Although as a businessman myself for many years, I never ran into the problems that we will spend several hours talking about today.

Quite honestly, Mr. Chairman, I chose the Small Business Committee assignment, and specifically this subcommittee, because I want to help small businesses. I trust that is still our goal. I look forward today to see how this hearing ties into the serious problems that small businesses face in this Nation.

Thank you, Mr. Chairman. I, too, look forward to working with you and other committee members.

Chairman WYDEN. I thank my colleague. I appreciate all of the comments of our colleagues.

I would also like to recognize any opening comments that our colleague from San Diego would like to make. Congresswoman Schenk is not a member of our subcommittee, but has asked to sit

in on today's hearing. She does represent the district where Scripps is.

I want very much to commend my colleague, the gentlewoman from San Diego, who has been a great asset in the work of this subcommittee on this issue. She has demonstrated extraordinary diplomatic skills in working with all parties to help get as much information on the table this morning as possible. She has done an extraordinary job in trying to bring the parties together.

We are very pleased that she is sitting in. I would like to recognize her for any comments that she would like to make.

Ms. SCHENK. Thank you very much, Mr. Chairman.

I would like to thank you for extending me the courtesy of sitting in with the subcommittee. I would like to thank the other members of the subcommittee for allowing me this privilege. You have been extremely gracious and considerate of my concerns in this matter. I want you to know how very much I appreciate your collegiality and generosity in this matter.

As you know, Mr. Chairman, Scripps Research Institute is located in my congressional district, and, in fact, it is a neighbor up the street. So, I know it well.

Scripps is the world's largest nonprofit biomedical research facility that is not affiliated with a university. It is a world leader in basic biomedical research. I am sure that Dr. Beutler, who will be representing Scripps, will discuss some of his distinguished work and the work of others at Scripps.

I want to preface my remarks by commending you, Mr. Chairman, for your continued efforts in examining the Federal laws which govern biomedical research and the contracts attendant thereto.

You are well aware of the importance of this research to the development of new treatments for life threatening diseases. I, too, think that this is an important issue. I am as every bit as interested in fighting any fraud, abuse, or conflicts of interest which might occur in biomedical research.

Should Scripps or any other institution be guilty of any such actions, I would, Mr. Chairman, be right beside you in assisting you in your efforts.

It is not a secret that Scripps was somewhat reluctant to come and testify today. In my statement, I would like to make two general points, which I think will shed light on why they hesitated.

First, from what we know about the proposed Scripps-Sandoz contract, it is legal. Funding arrangements between private firms and research institutes are sanctioned and encouraged by the Bayh-Dole Act of 1980. In fact, most major research institutions have a mix of private and public funding. Scripps derives between 60 to 90 percent of his funding from public sources, such as the NIH.

The document that Scripps has provided to the NIH suggests that Scripps' personnel have followed the letter and the intent of Federal law in negotiating its arrangements.

The subcommittee should question and examine the wisdom of existing law. I know that the chairman is concerned about possible increases in the price of pharmaceuticals, which he feels might result from such funding arrangements. I would support his in-

quiry into this matter. However, we should not prematurely judge either this situation or the principles involved.

Perhaps the NIH should be required to actually practice real oversight on these types of private/public arrangements. I know that the chairman is distressed by what he perceives as a lack of regulation by the NIH. But I respectfully suggest that today we should be gathering information, and not targeting a research institute which has seemingly followed the letter, and the spirit, and the intent of the very laws passed by this Congress.

I know that this is your goal, Mr. Chairman, to gather information, and to conduct a thorough review of the effects of the Bayh-Dole Act and other Federal laws. By their appearance here today, I know that Scripps is eager to assist in these efforts.

My second point is that Scripps' actions are not uncommon. These types of funding arrangements have become relatively commonplace since the passage of the act. Private funding often from pharmaceutical companies provides the bridge which turns basic research into lifesaving drugs.

As you noted, Mr. Chairman, the NIH has sent out over a hundred requests to other institutes and universities for details of their funding arrangements with private entities. When the Congress receives the results of this survey, I think that we will have a much better picture of the scope of this activity. Until then, we should recognize that Scripps is not some sort of aberration, but rather a representative of the biomedical research community, a community which enjoys legal access to private capital.

Again, Mr. Chairman, I thank you very much for this courtesy. This is a worthwhile inquiry by your subcommittee, and I support your efforts.

Scripps has come here to be a resource to the subcommittee. I appreciate that, and their testimony. I trust that we can all cooperate to work toward this common goal. Thank you again.

Chairman WYDEN. Again, I want to thank my colleague. She has done much to make this a helpful and constructive hearing, and I appreciate her involvement. We will work with her closely.

We are going to first recognize Dr. Bernadine Healy.

Dr. Healy, before I swear you in and proceed, let me first tell to how much I have enjoyed the excellent working relationship that this subcommittee has had with you during your tenure.

From our very first conversations, you recognized the critical role that the NIH mission has with respect to small business. As you can see, a number of our colleagues are very interested in this question. I know that as we talk about, for example, the mandate under the Bayh-Dole Act with respect to promoting small business employment, jobs, and entrepreneurship, that we are going to get into these issues.

In addition to the help that you have given us on Scripps and Sandoz, let me also note that of which you have given vis-a-vis nutrition and biotechnology. Finally, I want to note that we are going to continue to rely on your expertise and your information once you are out of Government.

Dr. HEALY. Thank you.

Chairman WYDEN. As you know, having appeared before, it is the practice of this subcommittee to swear all witnesses who come before the subcommittee.

Do you have any objection to being sworn?

Dr. HEALY. No.

Chairman WYDEN. Please rise and raise your right hand.

[Witness sworn.]

Chairman WYDEN. We also welcome Mr. Adler, who has been a frequent visitor to this subcommittee over the years, and your associate, Mr. Lanman.

Dr. Healy, do you anticipate that either Mr. Adler or Mr. Lanman will respond to questions today?

Dr. HEALY. Yes; I do.

Chairman WYDEN. Mr. Lanman and Mr. Adler, do you have any objection to being sworn as witnesses?

Mr. LANMAN. No.

Mr. ADLER. No.

[Witnesses sworn.]

Chairman WYDEN. Gentlemen, we welcome you.

Dr. Healy, your prepared remarks will be part of the hearing record in their entirety. Why do you not proceed as you see fit.

TESTIMONY OF BERNADINE HEALY, DIRECTOR, NATIONAL INSTITUTES OF HEALTH, HEALTH AND HUMAN SERVICES, ACCOMPANIED BY REID ADLER, DIRECTOR, OFFICE OF TECHNOLOGY TRANSFER, AND ROBERT LANMAN, GENERAL COUNSEL

Dr. HEALY. Thank you, Mr. Chairman. I will make abbreviated comments to start.

Mr. Chairman, and members of the subcommittee, I am here today to testify about research support agreements between academic research institutions funded by NIH and industry, and how they relate to small businesses.

Within that context, you have asked that we consider an agreement between Scripps Research Institute and Sandoz Corp. in the context of the policy objectives articulated by the Congress and the Bayh-Dole Act of 1980.

The mission of the National Institutes of Health is the pursuit of science to improve human health. Through technology transfer, the fruits of NIH-funded research are brought to the public by translating fundamental medical research into commercial products that improve human health.

In turn, this process has fostered the development of a strong U.S. biotechnology sector. The projections indicate that revenues for biotechnology will exceed \$50 billion by the year 2000 and produce thousands of jobs.

NIH's support of research has helped make the United States the world leader in pharmaceutical and medical devices industries, which are among the most promising sectors of our economy.

Central to this success is the Bayh-Dole Act, which governs the transfer of technology from NIH-funded research institutions to industry, as well as other agencies to industry. Through this Act, the Congress has encouraged collaboration between commercial con-

cerns and nonprofit organizations, promoted the patenting and licensing of inventions developed with Government funding, and given preference in such activities to small business firms and to those who manufacture in the United States in the interest of creating U.S. jobs.

In the interest of expediting technology transfer and minimizing administrative costs, the Bayh-Dole Act has removed the NIH and all funding agencies as middlemen in the process. Under the Bayh-Dole Act, institutions are automatically granted first rights to inventions, without prior agency approval. Clearly, under the Bayh-Dole Act, the NIH has more limited authorities than it had 10 or 12 years ago.

The act does allow, however, Federal agencies to intervene after the fact, so to speak, under specific conditions with so-called march-in rights. These march-in rights may be exercised if a specific invention is not being developed effectively, to alleviate health or safety needs, to meet the requirements for public use specified by the law, and if a product is not being substantially manufactured in the United States but will be sold in this country.

The Bayh-Dole Act effectively governs the bulk of NIH research, as it is converted into practical application by our universities and nonprofit institutions. More than 70 percent of NIH's resources of its \$10-plus billion budget supports research and research training in hundreds of extramural institutions throughout the Nation.

Clearly, the history of patent activity subsequent to the passage of the Bayh-Dole Act has shown that patenting and licensing are being pursued more aggressively. Most federally supported research leads to the creation of small businesses. So, indeed, the Bayh-Dole Act is of extraordinary importance to this subcommittee. But most importantly, the development of many new important drugs and devices by both large and small enterprises has been facilitated.

Since the enactment of Bayh-Dole, the climate for biomedical research and technology transfer has changed. Increases in NIH appropriations have not kept pace with the expanding opportunities, causing research institutions to look elsewhere for support.

Funding for industry research has increased. Science has become increasingly international. That means that partnerships are developing between U.S. industries and foreign entities, and small businesses and foreign companies.

The increasing success and the importance of the biotechnology industries have drawn attention to the international competitiveness of this industry, and clearly to the issues of foreign access to U.S. discoveries. For these and other reasons, the return on the public investment in research and development is being scrutinized more closely. More jobs, new products, royalties, and lower prices are the appropriate return on that investment.

To this question, the Bayh-Dole provides only limited guidance and flexibility. Notably, however, Bayh-Dole does allow for an exceptional circumstance determination to be made when a grantee's right to retain title to any subject invention will better promote the policy and objectives of the act, if there is a restriction on those rights.

Joint ventures between nonprofit research institutions and industry have proliferated over many years, but they have also become much more complex. A just-released study by the Congress' Office of Technology Assessment [OTA] entitled "Pharmaceutical R&D: Costs, Risks and Rewards" has identified 25 large-scale, multiyear pharmaceutical arrangements between industry and academia.

The majority of these arrangements, however, were between U.S. academic institutions and U.S. industry, and focused specifically on individual products and individual projects. The OTA did note, however, that relatively little is known about these arrangements in the long term.

The Bayh-Dole Act articulates multiple policies and objectives, which may prove difficult to reconcile, and we should note that at the outset. For example, an action by a nonprofit organization, while clearly advancing one objective of the act—such as promoting collaborations between commercial and nonprofit organizations—might not advance, and may, in fact, appear to undermine other objectives of the act, such as promoting free competition and enterprise.

Needless to say, application of the objectives of Bayh-Dole require a balancing of statutory objectives, but most of all with the overall best interest of the American public.

We must also remember that the general intent of the legislation is to promote product development, not commercial monitoring. Under the current Federal statutes and regulations, grantees and contractors are, except in limited circumstances, given broad discretion to elect title and license inventions made under Federal grants.

Within this broad authority, the Scripps-Sandoz case raises a number of policy issues. In order to assess this matter in a judicious, thorough, and fair manner, NIH has asked Scripps for its commercial agreements. We have also asked more than 100 other grantee institutions for copies of commercialization agreements relating to NIH funding in which institutions grant to industry exclusive rights. We have received very good cooperation from those inquiries.

On February 9, pursuant to a request from this subcommittee, NIH requested specifically that Scripps promptly provide a copy of its agreements with the Sandoz Corp. and with Johnson & Johnson, and similar agreements with other companies.

The NIH received copies of Scripps' research agreements with Sandoz, Johnson & Johnson, and Pittsburgh Plate Glass on Monday evening, March 8. My staff, including our legal advisor, Mr. Lanman, and the Director of NIH's Office of Technology Transfer, Mr. Adler, and I have initially reviewed the Sandoz agreement, which exceeds 100 pages.

Based on our preliminary review, the agreement raises several serious concerns regarding its conformance with both the spirit and the letter of the Bayh-Dole Act. Moreover, on the face of it, the agreement does not appear to serve the best interests of biomedical research, the American public, and U.S. competitiveness.

Moreover, it appears to be substantially different from the industrial agreements prevalent with most other NIH grantee institu-

tions that we are aware of. Accordingly, we will conduct a comprehensive review of this complex document. If our concerns are validated, we will pursue making an exceptional circumstance determination under our Bayh-Dole authorities. Such a determination would give the NIH the right to impose restrictions as necessary on its grant portfolio to Scripps, to ensure that the objectives of Bayh-Dole are met. We will also consider exercising our march-in rights under Bayh-Dole, if we deem that necessary.

As we proceed, we are ever mindful that the policy debates which relate to the Bayh-Dole Act and technology transfer touch all Federal agencies and hundreds of institutions.

We must work with others to assess carefully the complex and emerging policy issues that we now face, in part because the Bayh-Dole Act has been so successful in fostering academic industrial partnerships. But most especially, because the performance of NIH research is a public trust, and that trust remains paramount.

Thank you, Mr. Chairman. I would be happy to answer questions.

[Dr. Healy's statement may be found in the appendix.]

Chairman WYDEN. Dr. Healy, thank you for a very helpful statement. I am going to open with a few questions, and recognize my friend from Texas for his, and our colleagues for theirs. We will all have about 5 minutes on the first round.

I share your concerns, Dr. Healy. It seems to me that under this agreement that Scripps has become a virtual subsidiary of a foreign corporation. The National Institutes of Health, in effect, becomes an industrial lab for a foreign company.

Let me start by asking you whether you have discovered any potential conflicts of interest as you look at this agreement.

Dr. HEALY. As you know, Mr. Chairman, our own conflict of interest guidelines have not yet been finalized, so, I will answer that in a very broad and general way. There are some provisions within the contract which appear to give Sandoz the rights to perform and support research in human pharmacology, namely clinical trials.

We have been concerned that, in conducting clinical trials, it is important that scientists not stand to gain personally from the fruits of their research, the findings of their research, particularly as such trials involve human subjects and human patients in the testing of drugs.

The Sandoz relationship is extremely tightly coupled to the institution, insofar as, under this agreement, a joint scientific committee was established to oversee special research which they are funding, which includes the development of the protocols, the execution of the work, and monitoring of the work on a regular basis. It also describes which scientists can work on those projects, and which cannot work on those projects.

One has to raise the question as to whether there might not be the potential for a conflict of interest. Particularly if some of the scientists who were working on those clinical research projects are, in fact, getting consulting arrangements from Sandoz as part of the contract as well. There is a provision for individual scientists to get personal financial return for their participation under this agreement.

Chairman WYDEN. The subcommittee investigators have found evidence that the president of Scripps has a \$60,000 per year consulting contract with Johnson & Johnson Co., who also enjoys an exclusive technology transfer agreement with Scripps. The president of Scripps also appears to own stock in a pharmaceutical startup corporation financed partially by Sandoz, which has an exclusive agreement with Scripps. This deal appears to pay the president of Scripps a \$15,000 per year fee, and gives him stock worth \$1.5 million purchased at \$25,000.

Do these examples pose potential conflicts of interest?

Dr. HEALY. Of course I have no personal knowledge of any of these arrangements, but I think the scientific community at large is troubled if research results are directly going to lead to personal gain for the scientist who is generating those research results. That can create a perception of a conflict of interest, if there is a direct linkage to financial gain. Sometimes those gains are unavoidable. We believe that institutions must set up appropriate monitoring mechanisms when necessary in order to see that a real conflict of interest does not develop.

But NIH is not alone in its concerns about the potential for conflict of interest in research of all types, not just in clinical research but research of all types which might be influenced by consideration of the personal gain that could accrue due to a financial linkage to the sponsor or the consultant who is providing resources.

Chairman WYDEN. I am very concerned about possible violations of the Bayh-Dole Act, particularly the provisions that are designed to promote entrepreneurship for small business opportunities.

As you look at the contract, have you found any possible violations of Bayh-Dole and particularly its provisions that relate to small business?

Dr. HEALY. Clearly, this is going to be the subject of much discussion, but in our review—and I had five of our lawyers review this extensively—there are a number of concerns that are raised with regard to Bayh-Dole, particularly the policy objectives of Bayh-Dole. The policy objectives clearly are competitiveness and free enterprise. They are giving preference to small businesses. It involves giving preference to American industry for the generation of American jobs.

I think that if one looks at the contract in the context of those policy objectives, one sees that broad options are being granted on all research supported by NIH funds at Scripps without Sandoz directly funding necessarily all of those projects.

You eliminate a small business preference by having the exclusive relationship up front on virtually all research that is being done and that will be done for the next 10 to 20 years. Small businesses are basically forbidden for having even access to Scripps. There are clauses that stipulate that other companies, including small businesses, cannot even have access for any extended period of time to the campus, that they cannot collaborate with Scripps scientists.

There is sort of a monopolistic tone, not only in terms of the inventions, future inventions, and future ideas, but that also extends to all of the scientists at Scripps. Scripps has at least 40 agreements with existing companies, most of them small businesses.

Under this agreement, when those agreements expire, Sandoz has a say as to whether or not those agreements can be renewed and has the right of review.

I am also concerned, and my colleagues in the field of the law are concerned, that the clause on U.S. manufacturing within the contract might violate the intent of Bayh-Dole. Specifically, it says that Sandoz understands that it must substantially manufacture in the United States, but it adds a clause which says that such manufacture will be conducted only as long as it is commercially feasible.

That clause does not belong in Bayh-Dole. In fact, the commercial feasibility clause, as it appears in Bayh-Dole, relates to a NIH grantee looking at the field for people who will license and develop technology. The grantee looks to see if they can find someone in the United States who can license and manufacture that technology, and only if they discover that there is no commerce in the States to develop it, will they then look elsewhere.

In this agreement, they have taken the commercial feasibility clause and moved it up front, saying that if Sandoz decides that it is not commercially feasible to manufacture in the United States, then that is an exception and that Scripps agrees to help Sandoz to use all reasonable efforts to get a waiver from the agency, so that Sandoz does not have to manufacture in the United States.

Chairman WYDEN. Let me make sure that I understand that. I think my colleagues need to understand just how serious this is as well. Am I correct in understanding that you say that under this agreement, Scripps would agree to help Sandoz get a waiver around the U.S. manufacturing requirement?

Dr. HEALY. Correct, use all best efforts.

Chairman WYDEN. Please proceed.

Dr. HEALY. There are other sections which we think are noncompetitive and monopolistic. One of the most intrusive, which we think violates the spirit of Bayh-Dole and also in some ways the spirit of science—clearly the spirit of investigator-initiated science that we feel is the keystone of NIH's success—is a clause about assumption.

In essence, it says that Sandoz can assume the research of a Scripps scientist, and take it out of Scripps, and move it to any of its own facilities anywhere in the world, theoretically including to Switzerland, and that the Scripps scientists cannot seek funding, alternate funding sources, to continue their research.

That seems to be not only against Bayh-Dole, but also worries us with regard to academic freedom and the rights of scientists to pursue their own ideas and pursue their own work.

Chairman WYDEN. Dr. Healy, I need to recognize my colleagues.

But let's just wrap up this first round. Could you tell us what would happen to NIH and what would happen to the mission of the National Institutes of Health if this kind of agreement proliferated in the days ahead?

Dr. HEALY. The global nature of this agreement, as well as the extraordinary intrusion into the day-to-day scientific activities of this institution, the fact that Sandoz runs the joint council that oversees all of the science at Scripps at an institutional level, the fact that Sandoz gets to put members on their board of trustees,

the fact that Sandoz brings numerous scientists onto the campus and excludes other scientists from coming on to the campus, I think that this could lead to our major research universities being locked up by a handful of major companies, many of them foreign.

I think that it would squeeze out small businesses. It would squeeze out other scientists. It would interfere with the spirit of science and free interchange.

I also think ultimately it would be intolerable to the scientific community. I do not believe that the scientific community would work under these restrictions.

One of the Members just talked about intrusive regulations. The regulatory requirements placed on scientists at Scripps by Sandoz are so major, I do not believe that American science could proceed, as it has in the past, if these kinds of agreements proliferated.

I also think that it is unimaginable that major research universities in this country would agree to the kind of agreement that we reviewed the past day.

Chairman WYDEN. I will ask some questions in a later round, but I would like to recognize first my friend from Texas.

Mr. COMBEST. Thank you, Mr. Chairman.

Dr. Healy, you obviously raise some very interesting areas of concern relative to this agreement. If I am not mistaken, you received that agreement yesterday?

Dr. HEALY. Monday night.

Mr. COMBEST. These are things that I think are very significant and should be pursued. Obviously, NIH will continue to look at this area, and come up with their decisions about what the implications might be on Bayh-Dole, and what the implications might be in regard to NIH's future dealings in this specific agreement.

What I would like to try to do is to focus on not the specific agreement as much as on the concept of Bayh-Dole and its relationship to this subcommittee. My main interest is in trying to do what we can through Government to work as a service to provide number one, in this particular instance, the drugs that are obviously good for this country, but also expand the opportunities in this area for small business as we can.

Under Bayh-Dole, not having read the law in detail, is there a number which is mentioned—small businesses up here come under numbers or categories, depending on how many people work for it—is there a small business designation on what constitutes a small business under Bayh-Dole?

Dr. HEALY. Mr. Adler.

Mr. ADLER. There is a reference, I believe, to title XII. Let me, if you would permit, ask my colleague. There is a statutory reference that defines small business. It is in the context of the small business statute. I am not quite certain.

Mr. COMBEST. I am not sure of title XII. Because there are again varieties of definitions that we use up here, depending on how there may be exclusions.

In your experience, Dr. Healy—and I also want to join my colleagues in commendation of the tenure which you have served there at NIH; it is exemplary of public service—what is generally the opportunity for a small business to involve themselves in the product which might be obtained through an agreement with NIH

for development research and eventual implementation of pharmaceuticals?

Dr. HEALY. At the most general level, I think that Bayh-Dole has been extraordinarily successful in encouraging the development of small businesses and in fostering healthy collaborative relationships between our major research institutions funded by NIH and small companies.

There are numerous agreements, many small startup companies which have developed as a result of NIH-supported work, and universities and research institutions across the country, which probably would not have developed were it not for the fostering legislation of Bayh-Dole. So, I want to stress that NIH's policies and its technology transfer policies have been extremely supportive of Bayh-Dole, and I believe that Bayh-Dole has been successful and extremely supportive of small business development, as well as of free commerce and free enterprise, both of which are necessary to the development of these small companies.

The NIH in its own intramural laboratory has numerous cooperative research agreements with small businesses. In fact, the jewels of these biotechnology companies have been these small businesses that start around one idea that grew out of a basic NIH-funded research laboratory, and have grown up into major companies.

So, we think that our views and our concerns are probusiness, as Bayh-Dole is probusiness, and that this particular agreement between Scripps and Sandoz should not tarnish a 12-year history of magnificent collaborations between academia and industry.

Mr. COMBEST. I would agree with that as well. That one should not tarnish all of that good record. Unfortunately, many times we do not hear about all of the good things that happen. It is just the few things that create problems. I think that promoting small business is the main interest of mine.

Would you suggest that there needs to be changes in Bayh-Dole to be more accommodating either to small business or to give you more of a latitude in trying to look at agreements such as the one which you spoke of earlier, Sandoz/Scripps, and possibly allow you to enter into that process sooner and earlier, therefore, making it more certain that you might be able to catch these things prior to the time that the final agreement is reached?

Dr. HEALY. I think that under the statutory authorities NIH holds under Bayh-Dole, most of our responsibilities attach at the level of the invention. Once the invention is made, then NIH must be informed about the invention through a disclosure, and NIH must be informed if the institution will elect title and file for a patent.

The NIH does not have any authorities under Bayh-Dole to look at up-front, option-type agreements of the sort that we are examining here. What troubles me most of all is that many institutions, not just Scripps/Sandoz, believe that it is not the NIH's business to review collaborative arrangements which involve predominantly NIH-funded science.

Now, if a company is going to enter into a relationship with our grantees which does not involve Government money, I would agree that NIH has no right to review those documents. But I think that we at NIH believe that if an arrangement is going to be made

which substantially involves NIH and taxpayer-supported research, then the NIH should be allowed to review those documents.

Most importantly, NIH cannot fulfill its obligations under Bayh-Dole with regard to U.S. manufacturing, U.S. jobs, free enterprise, competitiveness, and small businesses without looking at those agreements up front. So, we believe, and our lawyers believe, that by virtue of the requirements and the policy objectives of Bayh-Dole, that we do have access to those documents. The auditing authorities of NIH do give us access. But there appears to be some legal disagreement on the part of some institutions that we do not have that right.

Our lawyers steadfastly say that we do. But I think that we might need some clarification, possibly in the form of regulations. It may not require a statutory change.

Chairman WYDEN. Would my friend just yield on that point very quickly.

Mr. COMBEST. I would be happy to yield.

Chairman WYDEN. Dr. Healy, we are looking at this deal because it is the largest and the most comprehensive. We are concerned that it could become a model for others. But as we look at our inquiry, we are very troubled about this matter upon which you have touched.

As you talked to these institutions, had one or more of them actually asserted that they are under no legal obligation to let you to see these contracts that are lubricated with taxpayer money?

Dr. HEALY. I will say that the majority of the institutions have been extraordinarily cooperative, have raised no objections whatsoever, have freely responded, asked a few questions, and have asked for delays, but overall have been extremely cooperative and forthcoming with regard to when and how they grant exclusive licenses.

There have been one or two exceptions. I have here one institution that writes,

We do not agree that the cited regulations grant you the authority to receive copies of these documents, nor in our view do they require Baylor to produce these documents, as part of an overall audit of the subject grants.

Of course, Scripps has written and said, "Scripps firmly believes that it is not required to comply with NIH's request."

So, there are a handful of institutions which believe that we do not have these authorities, and have resisted giving us the documents that we have asked for.

Mr. SISISKY. Would the gentleman yield?

Chairman WYDEN. I would be happy to yield.

Mr. SISISKY. These institutions that say that you do not have the authority, you have no obligation to give them the grant—do you? I mean, I do not understand. You have the leverage. If you do not have the authority, who gave them the grant? Or is it by law that you have to give them the grant?

Dr. HEALY. Of course not. That is discretionary money.

Mr. SISISKY. That is what I am saying. That gives you the authority.

Dr. HEALY. Our lawyers have given us a determination—and I might ask Mr. Lanman to speak to this—that if an institution fails

to comply with our auditing request, that we have the authority to restrict or withhold their grants.

Mr. LANMAN, would you like to expand on that?

Mr. LANMAN. Yes; the authority is found in our regulation which we have cited to these institutions. Based on that regulation, if the institution fails to comply, we could first suspend funding of the grant, and then terminate it after they have the right to exercise an appeal, an administrative appeal.

Because of that process, it could be a fairly lengthy type enforcement effort in order to get what we are really after, a copy of the agreement.

Mr. COMBEST. Doctor, if I might follow up on this as well, the area where I was going when we began to have additional comments, which I think were very worthy on the subject.

At that point I was asking if you felt like it might be better if NIH had an opportunity to come into the picture earlier in terms of these agreements, since what basically happens, I presume, is that they are agreed to, and then they are sent to you at your request, but really much already finalized.

The only way you have, I presume, to deal with these, other than a blatant violation of the law which I would presume would be dealt with otherwise, but in terms of NIH, would be withholding of funds for grants to that specific company where the agreement in your opinion did not live up to Bayh-Dole?

Dr. HEALY. We have other, less strong steps that we can take. We have the authorities under Bayh-Dole certainly to march in to see that there would be nonexclusive licenses granted in the event that we think that there is a violation of the policy objectives of Bayh-Dole.

We also have the right to make an exceptional circumstance determination, in which we could say that there would be certain restrictions imposed on grants made to a given institution that is governed by a research agreement that we believe is in violation or is questionable with regard to Bayh-Dole. Those restrictions again could deal with the issue of whether exclusive licenses could be granted.

So, we do not have to go to the extreme, which I think would be damaging to science and scientists, of interrupting the grants, but rather put specific restrictions on how the fruits of science are commercialized in order to assure compliance with Bayh-Dole.

Mr. COMBEST. I will finish with this one, Mr. Chairman.

Has it been uncommon or has it happened in the past that, as companies are working on agreements, NIH will eventually have the opportunity to review for compliance with Bayh-Dole? Has there been an early weigh-in on areas that companies may have had questions of how that might be interpreted, that they would come to you prior to the time that an agreement was reached to see what your suggestions would be?

Dr. HEALY. We actually have a history going back many years of institutions coming to us, particularly in the context of large research agreements, large industrial academic agreements, that are likely to attract attention, or that effect a large amount of NIH research, that institutions very often come to us, show us the con-

tract voluntarily, ask us what our views are, and ask us to help them with it.

I think that has been a very positive track record of cooperation between NIH and our grantees. Again, we and the bulk of our institutions come at this with a very positive feeling about technology transfer, about academic industrial collaborations, and about all of the policy objectives of Bayh-Dole.

Mr. COMBEST. I will just end with this. I think that you are exactly correct, as Mr. Sisisky had pursued, that with American taxpayer dollars that are going into companies in huge amounts for research, obviously the rewards are probably countless when you look at the developments of technology and of pharmaceuticals in this particular instance.

There is a major responsibility, I believe, that the companies have to the Government and to those who are watch dogs to make certain that those moneys are expended wisely, and that there are not abuses, because it is those few cases of abuses that create, I think, the blight on a lot of programs that 99 percent of the people benefit from. It is those that we seem to focus on.

I appreciate your candor this morning in discussing this specific agreement which you have looked at. I am sure that it will result in a lot of additional investigation in the future.

Thank you, Dr. Healy.

Thank you, Mr. Chairman.

Chairman WYDEN. I thank my colleague.

The gentleman from Nevada.

Mr. BILBRAY. Thank you, Mr. Chairman.

First of all, let me understand, Dr. Healy, how much money does Scripps get on a yearly basis from the NIH?

Dr. HEALY. It received from the NIH about \$70 million in fiscal year 1992. It also receives Government money from other agencies, including the Department of Defense and the National Science Foundation, but not of that magnitude.

Mr. BILBRAY. Also, you brought up the fact that you may need regulations or you may need codification into law of some provisions. The NIH authorization, of course, is right on the floor right now in the House. I believe that our chairman will probably be a conferee on that particular bill. If you would provide us with suggested language that would enable you to enforce and actually cancel these contracts and so forth, I am sure the chairman would be more than willing to take that into conference and try to get it in this time. I am speaking for him, but I presume that would be true.

Chairman WYDEN. I would like to hear Dr. Healy's views. But my colleague has a very important point and an interesting suggestion. I do not know what the rules are with respect to bringing up new matter at this point. But I am certainly going to follow up on the gentleman's suggestion. I would be interested in Dr. Healy's views.

Dr. HEALY. I think that, at this point, probably it would be premature for us to decide that we would need a statutory change or a regulatory change. My lawyers here have said that some of the clarifications that we need could be achieved in regulation.

We also know that, under Bayh-Dole, the agency responsible for regulation is the Department of Commerce, not the National Institutes of Health. So, even though we are involved in the majority of the technology transfer cases with our civilian research institutions, the fact is that we are not the ones responsible for those regulations.

I think at this point that it would be difficult for us to give you that answer, but we might be able to do so shortly. I might ask Mr. Lanman if he would like to make further comment.

Mr. LANMAN. I have no further comment on that, except to again emphasize that it is the Department of Commerce that is responsible for implementation of the Bayh-Dole Act. So, anything that we would do would have to be done under their leadership, and in close consultation with them.

Mr. BILBRAY. Our chairman is also on that committee. That authorization has not shown up, so I think we have an opportunity. But if you could get to the committee the suggestions they could be codified because codification, is much stronger, and cannot be challenged like regulations can be. It seems to me, that we have got a serious problem.

How did this come up, how did this Scripps agreement come to the forefront; did it come through a whistle blower, or did it come because you heard about it or the committee heard about it? How did we find out about this agreement?

Dr. HEALY. There was a report in Science magazine last December, which was announced, I think, by the institution. The article, I think, captured the attention of many people, including people in San Diego, as well as that of the chairman.

Mr. BILBRAY. How many more of these could we have sitting out there like this that did not have a public announcement? Are we going to have hundreds of these cases that are out there like this, or is this just an abnormal aberration?

Dr. HEALY. Of course we do not know precisely, and we will not know until we complete our review of the major grantees, the 104 grantees. From what we can determine at the present time, based on the initial responses, we are not likely to uncover other such situations.

I will quote from one institution that said something which is said by many institutions in their response,

The university does not extend license rights to future research generally, but only to technology arising in the course of research done pursuant to a specifically agreed on research protocol to be sponsored by that licensee.

Also, at the time that the Scripps/Sandoz arrangement was announced, there was the statement that this arrangement is unusual, that this is different, and that this kind of arrangement might proliferate. From what we can determine at this point, it does appear to be somewhat in a class by itself. We hope to be able to give you more precise information within the month.

Mr. BILBRAY. The last point on this is the fact that under Bayh-Dole there are two agencies that are supposed to monitor implementation of this agreement in compliance with the act, the GAO, and the Department of Commerce.

Do you believe that these agencies should revisit their regulations—I think that you have made that clear that Commerce should, but how about GAO—and what changes would you recommend? You will get those to us, I presume?

Dr. HEALY. Certainly the Comptroller and the GAO have direct responsibility, as stated in the Bayh-Dole Act, to oversee the activities that are ongoing between agencies and their grantees and industry. I would think that it would be most appropriate to have the GAO play a role. The OTA just conducted a major study of such agreements, large and small. They commented that the large type of arrangements, which are similar but not identical to the ones we are discussing today, are less common, but may be increasing, and that a lot is unknown about them.

So, I think that now with a 12-year record on large arrangements, with newer kinds and more-intense large arrangements developing, that it might be the time for the GAO to take a look.

Mr. BILBRAY. Do these institutions have to send you copies? If we had a law that says that when grants are involved, that the institutions have to provide you with copies of all agreements prior to approval, would that kind of authority power really enhance the ability of either yourself, or Commerce, or whoever is monitoring?

Dr. HEALY. The difficulty is that you should only receive something for review if you are really going to review it, and you are going to make some decisions based on that. At the present time, we do not have any authorities to comment or to intrude ourselves in the relationships that exist between our grantees and industry. I am not sure that is a good idea.

I think that within the system of Bayh-Dole, NIH has gotten out of the middle. The NIH is not the middle man or the middle woman in these arrangements. It has fostered, I think, a rather speedy technology transfer mechanism.

However, I do believe that there must be some balancing of public interests to ensure that when major agreements are developed in which rights are essentially sold to NIH research up front many, many years before they may even be conceived or developed, that the NIH does have some participatory oversight responsibilities.

I also think that what we have to do is try and balance the issue of fostering technology transfer, at the same time protecting the public interest. What additionally I think concerns us all here is that this is not just an agreement in which you have such monopoly created for a large portfolio of NIH research, a monopoly on brain power, a monopoly on talent, as well as a monopoly on future inventions, but it is at the risk of sounding chauvinistic, it is with a non-American company.

I think that also should be scrutinized, if we believe that the U.S. competitiveness outlined in Bayh-Dole, particularly the preference for U.S. industry, the preference for U.S. manufacturing, and the preference for U.S. jobs is meaningful. If we believe that is important, I think that whenever an arrangement is made with a company that has major capabilities for manufacturing outside of the United States, and, in fact, some intention to do so, that we ought to scrutinize those agreements more carefully.

Whether NIH is the right entity to do it, or whether it is Commerce, I think that really has to be explored.

Mr. BILBRAY. Thank you.

Chairman WYDEN. I thank my colleague.

The gentleman from Massachusetts.

Mr. TORKILDSEN. Thank you, Mr. Chairman.

Again, Dr. Healy, thank you for your testimony in this area. Just to explore a couple of possibilities.

One, would it be possible either under existing regulation or statute for you to ask any recipient of a grant from NIH that any agreements that they enter into do comply with the Bayh-Dole statute as it is now written; is that something that you could do?

Dr. HEALY. Yes; and, of course, all institutions have an obligation to abide by Bayh-Dole. The Bayh-Dole Act really speaks to them more than it speaks to the funding agency, and it is expected that they must comply. What has occurred here is some ambiguity in which the Scripps Institute believes that its relationship with Sandoz does comply. In our review, we have some questions about whether it applies.

Mr. TORKILDSEN. Also, in general terms, I know that canceling a contract can be extremely time consuming. It sounds like it is simple, but sometimes it can take forever.

But is it possible, again, either under statute or regulation that if you found that a company was not in compliance with Bayh-Dole or some other statute that they were required to comply with, could you simply withhold from them future grants which sometimes is every bit as effective as trying to cancel an existing grant; is that something that you could look at?

Dr. HEALY. Since we award our grants on an annual basis, we always have those authorities. But that is kind of a big club. What we want to do is promote science and promote technology transfer. I think that our view is that something like an exceptional circumstance in which you would put a limited restriction on the grant, and allow the scientists to continue their science. But only put a limited restriction, which might be something like if an invention that comes from this research is to be licensed, then one cannot grant an exclusive license without prior approval of the NIH.

Now that would not be nefarious in the sense that it would intrude upon a scientist's independence, which we do not want to do. But it would put some restrictions on the subsequent commercialization of that research, which is funded in large part by the U.S. Government.

Mr. TORKILDSEN. The final question is a very, very broad area. In the world that we are living in now, it is extremely difficult to restrict the free flow of ideas, and people, capital, and virtually everything else, it seems, in each year that goes by.

Even if an agreement does not have a clause that says a parent company may be able to transfer the research of a scientist from the company receiving a NIH grant to the de facto parent company, is there any way that you would foresee that you could prevent that from happening? Because basic research or any type of research really can be done in a variety of countries and by a variety of companies.

Is there any practical way that you can see those restrictions? I mean I agree with the intent. We want the availability of the manufacturing here in the United States from research funded by the taxpayers. I mean absolutely that is what we want to see.

But as we become more of an international world, do you see a practical way to really enforce that?

Dr. HEALY. Of course, we are not in any way trying to restrict the free flow of ideas, the free flow of science, or scientists. On the contrary, this particular arrangement that we reviewed the past day puts in requirements that seem to do that, that seem to restrict, and, in fact, clearly do restrict science and scientists; who the scientists can talk to; what scientists can come on the campus; whether a scientist can continue to pursue their own research and their own discovery; who they can collaborate with; with whom they can have consulting relationships; and whether existing relationships between Scripps and its scientists with 40 other companies may be continued or renewed.

So, I am concerned that this agreement is against the spirit of free flow of ideas. The only thing that NIH, or Bayh-Dole, or technology transfer principles are restricting—if you can call it a restriction—is the matter of when an idea, which is a piece of intellectual property, is patented or how it is commercialized. If that patent or that idea, that piece of intellectual property, has been developed by U.S. taxpayer money, we believe that the U.S. taxpayer should benefit.

We also believe that taxpayers should not only benefit in terms of the product that will help their health, but also in terms of the economic development of that product, which will create jobs and create American industry.

So, we are not just talking about restricting science or scientists, a flow of those entities. We are also talking about making sure that the American taxpayer gets a return on its investment in biomedical research in human terms and in economic terms.

Mr. TORKILDSEN. Maybe I did not phrase it in the best way, but that was the gist of my question. I mean that is the one restriction that I believe is quite legitimate. Because this is U.S. taxpayer funded research, there should be a direct benefit, if there is any, here in the United States. My concern is that is just becoming more and more difficult to enforce.

I was asking that either with possible regulatory change or statute change, do you see that we will be able to enforce that in the future?

Again, I have not read this agreement, but just a general question. Are we going to be able to really ensure that taxpayer funded research does benefit primarily the United States? Obviously, there are going to be benefits elsewhere.

Are we going to have that ability with that one restriction that it does come back here to the United States?

Dr. HEALY. I think that these problems can often take care of themselves, if enough sunshine is put on them. I personally believe that if the entire scientific community and every one of our hundred grantee institutions were able to spend time with this particular contract, which my colleagues and I reviewed for the past day or 2 days, that the problem would be self-correcting.

I do not believe for a minute that the scientific community or research institutions would enter into these kinds of arrangements. I would like to have that dialog first before we take more action to forbid or restrict activities. My concern is that this agreement forbids too many things. It forbids free enterprise. It forbids exchange of ideas. It forbids free communication with scientists.

I think that is against the spirit of science as much as it is against the public interest. If this contract were out in the sunshine, and everybody could see it, I think that the problem would be self-correcting. Maybe that is the dialog that we have to have first before we move to the next step.

Mr. TORKILDSEN. OK.

Dr. HEALY. Mr. Adler wanted to make a comment, if he might.

Mr. ADLER. The Bayh-Dole Act generally treats U.S. companies not in terms of ownership but in terms of where the entity is located. So, I noted, for instance, Sandoz's statement for the record at the hearing this morning states that Sandoz employs 10,000 people in the United States, and pays tens of millions of dollars in taxes. As far as Bayh-Dole is concerned, interactions with Sandoz USA are with a U.S. company.

In the biotechnology field particularly, we have to be very careful about the nature of research. Because just like gene research or AIDS research, it has become very international in character over the last decade. The way that small biotechnology companies secure strategic marketing partnerships or supplementary funds in time periods when venture capital is tight is by turning to partners overseas.

So, one must take a very broad view of U.S. benefit when thinking about how the biotechnology industry itself would function with excessive constraints on its ability to interact on a worldwide scene.

Mr. TORKILDSEN. Thank you, Mr. Chairman. I yield back the balance of my time.

Chairman WYDEN. I thank my colleague.

The gentleman from Virginia, Mr. Sisisky.

Mr. SISISKY. I am sorry, but I do believe in the golden rule. Whoever has the gold, rules. That is why I made the statement before. We have the leverage. By "we" I mean, the U.S. Government. We are giving away \$7 billion. I am just amazed at the number of grants to nonprofit organizations I see listed here.

How do you audit these grants? Do you audit to be sure that this money is spent in developing products, or do you audit where this money goes?

Dr. HEALY. In scientific pursuit, auditing occurs all of the time with regard to the actual science, and how it is pursued, and how it is developed. I think that the system is quite healthy in that regard. Our auditing responsibilities typically are in the realm of auditing the financial issues; the grant dollars; the budgets; auditing compliance with Government regulations, like humane treatment of animals; recombinant DNA biosafety issues; and, of course, human subjects investigation.

So, we have extensive auditing. Some of it is conducted by the Department of Health and Human Services. Some is done by the Office of the Inspector General.

We also monitor, as do other Government agencies, like OTA and GAO, overall trends that examine return on investment to the American taxpayer, in terms of their health as well as economic issues.

Mr. SISISKY. When I talk about audits, I am reminded of another investigation of indirect costs—where universities are using money for purposes other than those spelled out with the grants.

Do you have that type of auditing?

Dr. HEALY. The Department of Health and Human Services has the responsibility of auditing indirect costs.

Mr. SISISKY. I noticed that you talked about commercialization.

What do we do when somebody wants to commercialize a product? You said that you have the right to make sure U.S. taxpayers benefit from their investment. How do you do that?

Dr. HEALY. Of course, we encourage commercialization. The typical way in which NIH monitors it is our requirement under Bayh-Dole, which stipulates that all grants have on the very front page a statement as to whether there are any patents or inventions that have resulted from the research. We must include that statement in our grant agreements, and that allows us to keep track of all of the patents that have developed and all of the inventions.

Mr. SISISKY. Other than monitor the products—

Dr. HEALY. The invention, the patent.

Mr. SISISKY [continuing]. That would contribute to the health or welfare of Americans, what else do we do? Do we control the price to any degree?

Dr. HEALY. No; we do not.

Mr. SISISKY. We are going to get a lot of visitors in the next few days, Mr. Chairman, when we ask these questions.

Dr. HEALY. Mr. Wyden knows that we feel strongly that NIH should not be involved in setting prices for pharmaceuticals.

Mr. SISISKY. We do nothing?

Dr. HEALY. We are a science agency.

Mr. SISISKY. Well, wait a minute. I think that you said that in the commercialization process, you have the right to make sure U.S. taxpayers benefit from their investment?

What do we do? How do we protect the investment of American taxpayers, a \$7-billion investment now?

Dr. HEALY. What we do is we fulfill our obligations under Bayh-Dole, which are to monitor the development of patentable inventions. Institutions notify us when they are electing title. NIH keeps a portfolio of all invention reports, as well as patents. NIH has the authority and the ability to either march in or declare exceptional circumstances.

In our entire history, we have only threatened to march in in the case of one drug. For the most part, the system works very well, and NIH fulfills its obligation under Bayh-Dole. With regard to commercialization, under a law passed by this Congress, the NIH was removed as a middle man in the process of developing the up-front negotiations and the up-front contracts between our grantees and industry.

When it comes to the NIH intramural laboratory, which is about 10 percent of our portfolio, NIH is actively involved up-front in negotiating those contracts, and in industry issues that have to do

with fair pricing, and in industry issues that have to do with the constraints on those collaborations, and the return on the public investment.

But we have different procedures. When we are dealing with our own intramural Federal laboratory in Bethesda, we tightly control technology transfer. When we are dealing with our grantees, which is the bulk of our portfolio, those authorities under the law are for the most part delegated to the grantee institutions. We have only limited responsibility.

Mr. SISISKY. That is what I am saying. You said that you made sure U.S. taxpayers benefit, but you really do not. I mean we really do not have anything to do with it.

Am I correct in that? I think that is the answer to my question. That is why I could not understand your initial statement.

To what extent do you audit institutional rules regarding conflict of interest among employees?

Dr. HEALY. We have a requirement under the Public Health Service Regulations that all institutions must have conflict-of-interest rules. We have developed a set of model rules, which would be the standing PHS and NIH rules for conflict of interest, but they have not yet been approved or finalized. Until they are approved or finalized, again the responsibilities of conflict of interest and specific details of managing those conflicts of interest or perceived conflicts of interest remain in the hands of our grantees.

Mr. SISISKY. I do not mean to be critical, but didn't this start in 1987?

Dr. HEALY. What?

Mr. SISISKY. The conflict of interest problem. I have it here that NIH first started to address the potential for conflicts of interest. Are we still just talking about it?

Dr. HEALY. NIH does not have the authority to develop its own guidelines. Any guidelines that we develop must be approved by the Department of Health and Human Services. That may be hard to imagine of a \$10-billion agency—that we do not have the authority to develop our own guidelines—but we do not. We have had numerous drafts and sets of guidelines, but they have not yet been approved.

Mr. SISISKY. It is unbelievable. That's exactly what we are talking about.

If there is a conflict of interest in the Sandoz and Scripps deal, we have no enforcement mechanism, do we?

Dr. HEALY. I think that the major issues, our major concerns about the Sandoz/Scripps arrangement, have to do with compliance with the policy objections of Bayh-Dole. With regard to conflict of interest, there are certain sections that raise questions about it that need to be pursued. But it is impossible to determine whether there is a conflict of interest in this agreement. I would not go so far as to say that now. I think that has to be studied, and that information has to be gathered.

There is the potential for conflict of interest when you have scientists who have personal consultancy arrangements with a company, and then are doing research for that company where the results of their research will influence their own personal gain. But that has to be explored further.

Chairman WYDEN. If the gentleman would yield.

Just so we understand, the two potential conflicts of interest that you feel are important on which to follow up are: One, these personal consultancy contracts; and two, this matter of the human subjects research where there is funding going on?

Dr. HEALY. Yes.

Chairman WYDEN. Those are the two potential conflicts of interest that the institutes can follow up on?

Dr. HEALY. Right. On the consulting arrangements, it appears to be case by case where Sandoz must review any consulting relationships that Scripps scientists have. If it does not want them to have those relationships, it essentially can buy them out. It can buy out those consultancies by Sandoz, paying that scientist for what consultancies they could have obtained if they were under this agreement.

Chairman WYDEN. Sort of the Federal research equivalent to paying somebody not to grow crops?

Dr. HEALY. Maybe.

Chairman WYDEN. The gentleman from Virginia.

Mr. SISISKY. I know that you have raised a couple of concerns. The contract just got to you Monday night, so obviously you have nothing written on this.

But are there any other major concerns about this contract that you have not mentioned here today?

Dr. HEALY. One of the concerns that I think troubled us—there were one or two others—is that of the assumption of research, in which the company can go in and say that a certain piece of research should be taken away from a scientist and from Scripps, and that scientist then cannot pursue other funding mechanisms.

Another issue that certainly raised our concern was the fact that there is a scientific council, a joint scientific council, chaired by the company that oversees all research by Scripps, that can comment on specific funding projects with regard to who can collaborate and who cannot collaborate, which scientists can work on it, and which ones cannot. This council monitors research. This group meets at least four times a year, and most often its agenda is set by the company. It also puts two members of the company on the board of directors of the institute.

Mr. SISISKY. I am glad you said that just now.

How many members of the board do they have?

Dr. HEALY. As I remember, they have around six outside members.

Mr. SISISKY. They have six outside members. Now tell me a little bit about a nonprofit, that a corporation can demand seats on its board. I do not think that I understand that too well. The whole nonprofit nature kind of gets confused there when outside directors can control certain aspects of the nonprofit.

Dr. HEALY. They have only two seats on the board, but I do not know any further detail.

Mr. SISISKY. But they must exert some influence. It does not seem to me that the nonprofit has complete discretion from a scientific standpoint or in any other way.

Dr. HEALY. There is also a statement in there that Sandoz can ask Scripps to pursue research which is consistent with the strategic objectives of the company, of Sandoz.

Mr. SISISKY. A nonprofit organization. It looks like an extension of a for-profit corporation to me in a nonprofit environment, Mr. Chairman. Thank you.

Chairman WYDEN. I thank the gentleman for his questions.

The gentleman from Arkansas, Mr. Dickey.

Mr. DICKEY. No questions.

Chairman WYDEN. The gentleman from California, Mr. Kim.

Mr. KIM. Thank you, Mr. Chairman, for yielding time to me.

I have one question which I am going to ask bluntly, as that is the only way that I know how to do it.

Are you asking for more power and more authority so that you can control and regulate this abusiveness?

Or let me put it a different way. I seem to hear a conflicting message from you today. On one hand, you are saying that under the Bayh-Dole Act you are promoting commercialization, and promoting free enterprise, and technology transfer to small business, et cetera. Yet on the other hand, you mention that you need guidelines, and you need more direction. There is abusiveness of a grant-ee using Federal money to get advantage, secure these patents, et cetera.

You mention that these advantages should return back to taxpayers. Having said that, let me ask you two specific questions.

Number one, how do you return that to taxpayers? Do you have any idea how to do that?

The second question is what does it mean to small business? You mentioned several times that this would be a benefit to small businesses, the creation of small businesses, et cetera. I am not sure what the definition of small business is. How small is small business?

What kind of benefit would taxpayers receive, and also what does this mean to small business?

Dr. HEALY. The first question is the general question of the return of NIH research to the American taxpayer. I personally believe that there is no agency in the Federal Government that gives more return to the American taxpayer than the National Institutes of Health. It has a phenomenal track record of accomplishment in terms of bringing better health and improving human life. I think if it were well known in terms of what it has contributed to the American public, I think that NIH would be viewed as probably the jewel in the crown of the Federal Government.

That is mainly in the form of discoveries that relate to illness, that relate to cures, that relate to prevention, and that relate to alleviating human suffering.

The second question has to do with small businesses. Under Bayh-Dole, there is a specific statement that the technology transfer agreements must encourage the maximum participation of small business firms in federally supported research.

The Scripps/Sandoz arrangement, the global arrangement, that we are discussing today, would on the surface appear to keep small businesses away from the Scripps \$70 million-plus Federal grant portfolio. Scripps also currently has about 40-plus arrangements,

collaborative arrangements, mainly with small companies that have been going on for some time and are based on specific projects and specific areas of development.

This contract explicitly states that the company, Sandoz, will have some authorities with regard to overseeing and commenting on whether those agreements should even be renewed.

So, theoretically, even the existing small businesses that are gaining from federally supported research conducted at Scripps might be in jeopardy, due to Sandoz's authority to monitor any future renewal.

So, it is our belief that small businesses are not going to be getting ready access, if access at all, to federally sponsored research at Scripps under this very global and very tightly regulatory agreement.

Mr. KIM. Do you think that it is more efficient that you do it, the agency, NIH?

Dr. HEALY. We believe that the spirit of Bayh-Dole and the intent of Bayh-Dole should be adhered to. If you look at other big agreements like this—and the OTA has recently looked at them, there was a large one between Hirkson MGH, and there was a large one between Monsanto and Washington University in St. Louis—if you look at the agreements that those institutions struck with industry, they explicitly stated that scientists could have relationships with other companies, that these were not nonexclusive. They explicitly said that the company only got exclusive rights if the company supported most of the research that led to those exclusive rights.

They explicitly made sure that there was an arm's length relationship between the company and the management of those institutions. So, I think that those are the kinds of agreements that came up and developed without any intrusion on the part of NIH, but clearly supported the spirit of Bayh-Dole.

I recently saw that the Howard Hughes Institute has spoken out against the notion of exclusive bonding between one scientist and one company. Because they believe that it is in the public interest that scientists who are taking taxpayer dollars to do biomedical research should do that research on behalf of the American public, not on the behalf of a single company that buys present and future rights to all of their ideas, all of their grants, and all of the products that come out of their work for the next 10 or 20 years. I think that there is a difference.

Mr. KIM. Thank you.

Chairman WYDEN. Does the gentleman from California have additional questions?

Mr. KIM. I disagree with part of what she said, but I am not here to argue. I got the answer that I expected, so that is enough.

Chairman WYDEN. I appreciate my colleague's questions, and I am going to have some additional questions myself. But first, I want to recognize my friend from Nevada.

Mr. BILBRAY. Yes; I had one additional question.

Dr. Healy and the other gentlemen who are here, I am deeply concerned. Remember, I mentioned the fact that there are violations in this agreement. But the stock transaction that Dr. Lerner received as part of this agreement, in which Sandoz put \$9 million

into a company whose stock he got at a penny a share troubles me. The stock is now selling for \$7.50 a share.

Is this of any concern to NIH, the fact that this sweetheart deal was given to him? We do not know what this company is going to do. It has got a lot of money put into it, and it is going up. It is going to enter the biotechnology area. I can just conceive that many of the areas that it will enter will be the areas that we are researching and that we are putting our money into.

Does that bother you at all?

Dr. HEALY. Well, first, I cannot comment on the specific arrangements that you are mentioning, because I do not have any details of them. But in a general sense, it is not unusual for a scientist, one of our grantees, a scientist within a university or research institution who has an idea or holds a patent on a discovery, to be participating in the startup of a new company. They might get equity interest, or they might get interest with regard to membership on boards, participation in the scientific advisory role of the company, and the future scientific directions of the company.

Mr. BILBRAY. Dr. Healy, Dr. Lerner runs Scripps. He is probably not the one who actually developed this particular technique.

Dr. HEALY. I do not know that. He is a scientist also.

Mr. BILBRAY. This is an SEC filing. That is why we have it here. It is a fact of life.

Dr. HEALY. Again, I think that we ought to look at that separately and apart from the very positive relationships in which NIH grantees are part of startup companies, and the only thing that NIH is specifically concerned about is making sure that, because of their equity interest, their own research integrity is not in any way compromised, because of the promise of financial gain.

We think that there are ways of assuring that through monitoring, through conflict-of-interest rules, that will not break the entrepreneurial relationship that starts small businesses. So, we do not want to throw the baby out with the bath water.

We still want small companies to start with great ideas that result from NIH support. But we want to make sure that there is both a perception, as well as real avoidance, of conflict of interest. We think that those two things can be reconciled.

Now, the specific relationships with Dr. Lerner, I just cannot comment on, because I do not know about them. I think that you have to ask them.

Mr. BILBRAY. Dr. Healy, it seems like somewhere along the line, and I know that some foreign governments do this, when they put money out to develop a technique, or a medicine, or whatever they are developing, some of them take back a percentage of any royalties of any money made on this particular product.

Have we ever thought about doing that?

Dr. HEALY. Well, in years gone by, the Government often reserved rights to inventions and was a coowner of inventions. Under traditions that developed in the 1970's and subsequently under the Bayh-Dole Act in the 1980's and 1990's, the Government has decided that the best way to promote commercialization and entrepreneurial pursuit of new industries, and small businesses, and jobs, and new products that benefit the public is to delegate those au-

thorities, to allow the institutions to elect title, and to allow them to have the financial gain.

That has worked well. We can see that the whole strength of the biotechnology industry in this country is in large part because we have allowed that kind of entrepreneurial spirit to drive industrial development.

I think that for the Government to retain the title to all of these inventions and try to develop industries just would not work.

Mr. BILBRAY. Not take the title, but I said how about just a small royalty like we do on oil lands. We take a percentage of the oil that is drilled out of it.

If we are putting up \$7 billion a year on research, could we not take a little bit of it?

Dr. HEALY. Well, we certainly do for discoveries that are made in our own Federal laboratories. When we give grants to universities, we believe that they are the ones who are taking the risks. They are the ones who are hiring the faculty.

Mr. BILBRAY. We are paying for them though.

Dr. HEALY. We pay for a portion of their expenses, not all of them.

Mr. Adler would like to make a comment.

Mr. ADLER. Yes; thank you.

There is a very helpful GAO report—perhaps their witness will expand on it—from May 1992, that surveys the impact of Bayh-Dole on universities in terms of filing patent applications and licensing patents to the private sector. The statistic that the GAO reports for surveyed universities in fiscal years 1989 and 1990 was over 2,000 patent applications filed, and it looks like approximately 1,400 license agreements, generating royalty income in excess of \$100 million. So, I think that Bayh-Dole, in fact, is working.

Mr. BILBRAY. If we had a little percentage of that?

Dr. HEALY. We get a big percentage when we have great robust industry, and lots of jobs, and taxpayers.

Did you want to say something?

Mr. LANMAN. Mr. Congressman, I did want to add that what the Government does retain under Bayh-Dole is a worldwide royalty free license to use that invention for governmental purposes. That is what is provided under the Bayh-Dole Act.

Mr. BILBRAY. Thank you, Mr. Chairman.

Chairman WYDEN. I thank my colleague.

Dr. Healy, just a couple of additional questions, because I think that you have covered the waterfront pretty well. Let me ask you first about the matter of patents, and the patent situation at Scripps. What we have picked up is that Scripps is something of a patent machine out there. They have upward of 100 patents.

My understanding of the Federal statute is that when there is Federal Government funding going into a patent, this in some way is supposed to be marked on the various documents.

Have you taken a look at the patents out there, and do you now have some concerns that perhaps Federal law is not being followed with respect to the patent situation?

Dr. HEALY. Mr. Adler has reviewed the patent portfolio.

Mr. ADLER. In fact, earlier this week, we ran a printout of issued U.S. patents to Scripps. It looked to be about 130 or so, half of

which bear the statutory requirement that Government funding be acknowledged. I note in the GAO report—in fact, I noticed this last night preparing for the hearing this morning—that it is typical for surveyed universities to file relatively more patent applications on industry-sponsored research, it appears, than on Government-sponsored research.

I do not know whether or not that is because a more aggressive posture is taken on non-NIH funding in terms of pursuing patents, or whether the research that industry or other sources support is more likely to be at an applied level involving a development-type patent application. So, the statistics about Scripps are consistent with what the GAO has found for 30 or so surveyed universities.

Chairman WYDEN. Let me see if I can get this straight.

Scripps gets 90 percent or so of its money from the Federal Government.

You all have pulled the patents, and about half of the patents indicate that they have some Federal funding is that correct?

Mr. ADLER. That is correct. It is a preliminary printout. We may need to consult a little bit further, but that is the preliminary assessment that we made this week.

Chairman WYDEN. So, it is possible, given the fact that 40 percent of the patents do not designate any Federal funding, that they may not be properly marked and that is not in compliance with the Federal law?

Mr. ADLER. That is conceivable.

Chairman WYDEN. With regard to drug company prices, Dr. Healy, let me talk for a second just about theory here. This is something that you and I have talked about on many occasions. In fact, you have been very helpful to me in even grasping some of this.

My concern here is that these kinds of monopolistic practices in addition to the detrimental effect on small business reduces competition in the drug company marketplace. This may be a factor, as we look at the prices of drugs where, in effect, the taxpayer has done the heavy lifting.

As you know, the subcommittee has been looking at these already, and we are going to be following the products that come out of this agreement.

Do you think theoretically that is an additional concern about this kind of agreement, that this kind of monopoly structure, amounting to a global monopoly that is essentially constructed, has the economic underpinnings for shoving up drug prices even higher?

Dr. HEALY. I think that could be certainly a final derivative. I think that I am worried about the competitive issue. Because when a proprietary company like Sandoz has the ability to oversee research, and to control disclosures of that research, to assume that research, and even take it out of the country, you have to have some concerns raised about whether that might even be used in a noncompetitive way, not to have certain areas developed, because it is not in the competitive interest of the company.

I think that monopolies are not good for setting fair prices or for encouraging quality. So, I prefer to see the spirit of Bayh-Dole, which is the spirit of free enterprise, free access, and free competi-

tion honored. I think that price is one of the things that you have to consider.

Chairman WYDEN. We need to look at where we go from here. You, of course, are going to continue your inquiry with respect to this agreement, and look at the more than a hundred other agreements.

But do you think that the problems that you all have uncovered thus far with respect to the Scripps/Sandoz situation are sufficiently serious that we ought to be looking and asking the inspector general from the Department of Health and Human Services to review that Scripps/Sandoz agreement?

Dr. HEALY. Well, I think that is certainly a consideration for the Comptroller General in the GAO, because I think that there does appear to be a difference of opinion with regard to what the NIH lawyers feel is potential noncompliance with Bayh-Dole and what the institution believes is full compliance with Bayh-Dole. I think that we are going to have to have that difference of opinion resolved. Clearly, it is going to have to be resolved before NIH, if it is deemed appropriate, makes any exceptional circumstance determination that might put restrictions on exclusive licensing to Sandoz.

We need to do a lot of work ahead of time. The expertise of either the Comptroller General, who has that statutory responsibility under Bayh-Dole, or the IG might be very helpful to us.

Chairman WYDEN. We will want to talk about that as well in the days ahead. One last question, if I could. A number of the members on the committee, really on both sides, have been concerned about the need for adequate restrictions, adequate protections to protect the public interest.

The argument, of course, or the refrain is when people talk about that is that it will hamper the ability to promote these partnerships and create jobs. Of course, people will suffer. People will suffer, and will not get cures, and the fruits of medical science will not be available quickly.

Are you of the view that it is impossible to strike a balance? I think that is what the Members here want. They want to make sure that the products get out of the chute quickly. At the same time, we have to be attentive to taxpayers, and we have to be attentive to the need to get these products on line quickly.

Have you heard anything here today that would suggest that we cannot have these collaborative agreements and, at the same time, protect taxpayers and consumers?

Dr. HEALY. I think that collaborative arrangements of the type that were fostered by Bayh-Dole are absolutely essential to the American taxpayer getting the return on the NIH investment. They are absolutely essential to NIH's pursuit of its mission to improve the health of the American people through discovery, because NIH cannot develop these drugs.

I would hope that this committee has the opportunity to review and celebrate the many, many superb academic industrial relationships that have grown up over the years among our grantee institutions, and see what truly good, positive, and effective arrangements look like. I think that I would like to see the committee get input from the community at large about the very positive protec-

tions that they have put in to protect the public interest, and to protect their own institutional interest.

I hope that we might be able to learn from some of these new emerging intrusions on Government-funded research that might be developing, and maybe see if we do not go down the wrong track and overturn an apple cart that has been very, very successful over the past decade or more.

Chairman WYDEN. Well, you have done much today to try to get this process back on the right track. It seems to me that you have delivered an extraordinary indictment of the Scripps/Sandoz deal. You have talked about aspects of this that are potentially detrimental to small business; serious potential conflicts of interest, and serious potential violations of Bayh-Dole, possible threatening of the mission of the National Institutes of Health, and threats to the independence of science.

In the days ahead, I want to see the kind of information that you have given us today about Scripps/Sandoz, in effect, to be looked at as an aberration, and that we have a much more healthy collaborative process for getting products to market, helping our economy, helping consumers, and carrying out what Bayh-Dole was all about.

As I noted in my opening statement, you have been a great help to this subcommittee in working with us over the years and identifying these issues that are so relevant to business, taxpayers, and consumers. I want you to know that when you go back to the private sector, when you go back to Cleveland, I am going to be calling on you often. We thank you.

Mr. Adler, we will look forward to seeing you in the days ahead.

Mr. Lanman, you will be welcome as well.

We will excuse you at this time.

Dr. HEALY. Thank you.

Chairman WYDEN. Next before the subcommittee is Mr. Ralph Nader, Washington, DC.; Mr. Jim Wells, Associate Director, Energy and Science Issues, U.S. General Accounting Office; Dr. Judith Wagner, Office of Technology Assessment, accompanied by Dr. Michael Gluck, senior analyst, Office of Technology Assessment; and Dr. Henry Etzkowitz, professor, Department of Sociology, State University of New York.

Dr. Wagner and gentlemen, we welcome you. It is the practice of the Small Business Subcommittee to swear all of the witnesses who come before us.

Do any of you have any objection to being sworn?

[No response.]

Chairman WYDEN. Please rise and raise your right hand.

[Witnesses sworn.]

Chairman WYDEN. Dr. Wagner, I know that you are on a tight time schedule. Mr. Nader is as well. Why do we not start first with you, Dr. Wagner, and then Mr. Nader. If I can ask you all to try to keep within 5 minutes, that would be very helpful, because we do have the NIH bill on the floor this morning. Dr. Wagner.

Dr. WAGNER. I appreciate your understanding in this regard.

We would like to submit our formal statement for the record.

Chairman WYDEN. Without objection.

TESTIMONY OF JUDITH L. WAGNER, SENIOR ASSOCIATE, HEALTH PROGRAM, OFFICE OF TECHNOLOGY ASSESSMENT, ACCOMPANIED BY MICHAEL E. GLUCK, SENIOR ANALYST

Dr. WAGNER. As you know, OTA recently completed a study of pharmaceutical research and development. Although we did not analyze the policy implications of the sizable Federal support for academic biomedical research, we did document the available data on Government and industry as funding sources. We are here today to provide you with a brief summary of that information.

Collaborative arrangements between academic researchers and pharmaceutical firms represent an indirect transfer of federally supported research and knowledge to the private sector. Although university/industry corroborations span the entire breadth of the pharmaceutical research and development process from its very beginnings to the clinical research area, we focus today on collaborations in the discovery phase, where research most often leads to the invention of a pharmaceutical substance or technology with potential value to the inventors.

The advent of biotechnology techniques in university laboratories in the 1980's began an expansion of collaborations as large pharmaceutical firms turned to academia to learn these techniques.

In many instances, the principal founders of the new biotechnology companies were academics who kept their university affiliations. Academic scientists also sought to commercialize university research through startup firms that also maintain close relationships with these laboratories.

Today's collaborations between universities and industry take place against a backdrop of pervasive Government funding for biomedical research and academia. Of the \$7.7 billion of NIH funding in 1991, over three-quarters went for research performed in higher education and other nonprofit institutions.

Even within the individual academic research laboratories, financial support from industry piggybacks on Government support. In 1984, the vast majority of biotechnology faculty who received any support, any research support, from industry still got most of their research support from Government and the nonprofit sector. Only 10 percent of principal investigators received more than 25 percent of their research support from industry.

We looked at four kinds of collaboration between academia and the pharmaceutical industry. The two most common are project-specific research support and second, consulting arrangements between faculty and pharmaceutical firms.

A study from the mid-1980's, which is the most recent data available, showed that industry funding of individual biotechnology research projects in academia accounted for between 8 to 24 percent of all funds available for such research. About 40 percent of biotechnology faculty had consulted with industry for money at least once in the previous 3 years. These arrangements may be much more common today with the growth of biotechnology since the mid-1980's.

The second two kinds of collaboration have certainly received more popular attention in recent years. They are the large scale, multiyear investments in academic research centers by private

companies, of which the Scripps and Sandoz arrangement is an example, and second, the ownership or control of industrial firms by a university or its faculty.

These less frequent arrangements have received a great deal of scrutiny, not only because of their novelty in the life sciences, but also because of their potential impact on traditional academic values.

A list compiled by Webster and Etzkowitz of most of such relationships with the pharmaceutical industry through 1990 was attached in our testimony. It shows that in 1990 alone, over \$150 million of industry money was committed to academic centers, most to be paid out over a 5- to 15-year period.

In the 1980's, many faculty in the life sciences founded companies with products or services based on their own research. In response to this trend, some universities have banned faculty from holding equity in firms that support the faculty member's own research, while others have relied on faculty disclosure rules in a case-by-case consideration of their appropriateness.

Although individual cases have been controversial, the scanty evidence that does exist suggests the phenomenon of faculty equity holding in commercial enterprises is actually very infrequent. In 1985, only 8 percent of faculty involved in biotechnology at universities reported holding equity in a firm whose products or services were based on their research.

The current prevalence of university/industry relationships is due, at least in part, to the Bayh-Dole Patent and Trademark Act of 1980. As you know, this law gave universities and nonprofit organizations the right to all inventions resulting from research. It also required universities to share any royalty income with the individual inventors.

Under the current law, the Federal Government has no legal authority to control or monitor how universities and nonprofit research institutions decide to award rights to research results produced on their campus.

I stand corrected, because I learned a great deal about the degree of control that the Government does have from Dr. Healy this morning. So, my last sentence is not totally accurate. But, in general, the legal authority is not there to oversee these agreements.

Thank you.

[Dr. Wagner's statement may be found in the appendix.]

Chairman WYDEN. Dr. Wagner, thank you. I know that you are on a tight time schedule. We will move along, and hope that we can get to some questions.

Mr. Nader, welcome.

TESTIMONY OF RALPH NADER, CONSUMER ADVOCATE

Mr. NADER. Thank you very much, Chairman Wyden, and members of the committee.

I am pleased to appear today to discuss the consequences of more than a decade of congressional and executive branch efforts to alienate taxpayers from ownership or control of publicly funded research and development.

As you know, this is a topic that has been neglected by the Congress with small exceptions, Small Business Committee exceptions, especially during the Reagan given-away years.

More recently, it has been the subject of numerous inquiries by our Taxpayer Assets Project, which focuses on the management of Federal information resources and federally funded pharmaceutical inventions. Taxpayer assets, I hope, will become a major and legitimate political issue in the coming years.

Most people hardly realize that tens of billions of dollars of information resources, federally owned natural resources, pharmaceutical and other medical research are subjected to a process which does not treat the equity of the taxpayer with very much respect, and also fosters, as has been noted earlier, all too often, monopoly practices or exclusive agreements, and other maneuvers which do not benefit consumers.

The Bayh-Dole Act, which gave certain profit and nonprofit organizations title to patents and other intellectual property rights on federally funded research, was really a reversal of Senator Russell Long's long attempt to make sure that federally funded inventions had their patents retained by the Government, and the Government, in turn, provided nonexclusive licenses.

Senator Russell Long's lonely endeavor in this area produced one amendment after another to ensure that principle. That principle was basically detonated by the 1980 Bayh-Dole Act. It was followed by dozens of congressional enactments and executive orders from the President, which has further eroded the public's ownership or control over important technology and information resources, and increased the private monopoly power of companies that sell these resources back to the citizens who paid for much of them or all of them in the first place.

In my testimony, I refer to the evolution of the Orphan Drug Act, the widely expanding use of cooperative research and development agreements, et cetera.

I want to remind the committee of the secrecy which underlies so much of this abuse. If you look at all the institutions that should have prevented the kind of situation that now afflicts Scripps with the Sandoz arrangement and the Johnson & Johnson arrangement, you will see that they range from the executive branch, inspector generals, NIH, HHS officials, congressional oversight committees, et cetera.

The opening inquiry into the Sandoz/Scripps agreement came from a disclosure, I understand this morning, in Science magazine. It was the media that opened the door.

But it continues on. Michael Ward of our Taxpayer Assets Project asked the J&J spokesman, Robert Kniffen, the following questions on March 5, 1993:

Question: "Does or did J&J have any contracts with staff or board members of the Scripps Institute?"

Answer: "Not to my knowledge, no."

Question: "Could I have a more definitive answer; could you check this for me?"

Answer: "We would not consider that anybody's business. Agreements we have with individuals are a private matter."

Now we go to the wisdom of Congressman Jack Brooks, who in filing a minority report on Bayh-Dole in 1980, made the following statement, which I think frames the philosophical underpinning which we should pursue:

The major problem I have with H.R. 6933 is that it violates a basic provision of the unwritten contract between the citizens of this country and their Government; namely, that what the Government acquires through the expenditure of its citizens' taxes, the Government owns. Assigning automatic patent rights and exclusive licenses to companies or organizations for inventions developed at Government expense is a pure give-away of rights that properly belong to the people.

The Federal Government has the equivalent of a fiduciary responsibility to the taxpayers of the country. Property acquired with public funds should belong to the public. Deviations from that fundamental principle should be allowed only where a compelling justification can be shown and where the voice of the public can be heard in protest.

Mr. NADER. I now want to turn to a summary of my recommendations for this committee to consider.

One, the Patent and Trademark Office should require that all patent applications include a summary of federally funded research which contributed to the discovery. There is now a process that is found more in the breach than in the acknowledgement by patent application.

Two—and I might say that this was a proposal that we made to the Subcommittee on Intellectual Property and Judicial administration of the House back in 1991 and has yet to be acted on—all Federal grant and contract recipients should provide uniform public reports to the Federal Government which disclose the terms of licensing agreements on research that was funded by the Federal Government and the income that is received from such agreements.

Three, all Federal grant and contract recipients should be required to disclose to the Federal Government and the public any potential conflicts of interest between the institution and the entities which receive the marketing rights to intellectual property developed with Federal funds.

Four, Congress should require all grant and contract recipients to provide nonexclusive licensing of technologies developed with Federal funds, unless permission is received from the Federal Government to use exclusive agreements.

I was pleased to see that Dr. Healy made some positive remarks on that point this morning.

That permission should be subject to a finding that the exclusive agreement is in the public interest under a procedure inviting public comments and public dockets. Proposed and final exclusive agreements should be available for public inspection and comment.

Five, the Federal Government should have the right to limit pricing on pharmaceutical drugs and other medical inventions. In determining fair prices, the Federal Government should take into consideration how much of a subsidy the taxpayer provided in this Government-funded research that ended up in corporate hands.

Six, information about the licensing of publicly funded research and development resources should be widely disseminated to interested consumer, taxpayer, and citizen groups, using such modern information technologies as the Internet and the National Research and Education Network.

Seven, the committee should inquire into the possible violations of the tax status of the Scripps Institute. This has to be looked at together with the Treasury Department. Or any other similar institutes that are engaged in this kind of interlock that you pointed out, Mr. Chairman, several times this morning.

Eight, standard setting or rulemaking by agencies have to adhere to the Administrative Procedure Act.

In the research grant and transfer areas, there is a large vacuum. There virtually are no standards that are invocable by the public, or even any standing rules. Properly suited accountability mechanisms should be developed for research grants, contracts, and joint ventures between Government departments, institutes, and laboratories, particularly since the Clinton administration is going to expand these areas quite extensively.

This tailored scope of due process should permit the public to be given proper notice, voice, and final review rights by a tribunal external to the granting organization.

The very presence of these accountability mechanisms would induce a more rigorous, honest, efficient, and reviewable decision-making process. It certainly would give taxpayers more value for their dollars. The ultimate beneficiaries, consumers, would receive the benefit of more competition and fairer pricing.

The Subcommittee on Regulation, Business Opportunities, and Energy certainly has the imagination to get this process started, and should do so promptly, to avoid a growing banality of exposés, that is followed by little institutional change in the executive branch. I am not just referring to the many good exposés by this subcommittee, Mr. Chairman. But there are far more good exposés coming out of Congress compared to any change that follows in the executive branch. There has to be a much more insistent focus on these institutional changes invocable by the public. Otherwise, there will indeed be a growing banality of exposés.

Thank you.

[Mr. Nader's statement may be found in the appendix.]

Chairman WYDEN. Mr. Nader, thank you.

Let me do a couple of things. We have a vote on the floor coming up.

First though, Mr. Nader, let me thank you for the help that Taxpayer Assets has given us. Mr. Love was very involved in working with us on the Taxol situation, which we continue to be very, very concerned about the way that the Federal Government has dealt with that. I am going to follow up on your suggestions.

I also want to note that the situation on page six of your testimony where the Johnson & Johnson spokesman said that Johnson & Johnson did not have any contracts with staff or board members of Scripps.

Late yesterday, a document from Johnson & Johnson that came into the subcommittee indicating that the president, I believe, Mr. Lerner, at Scripps, has a consulting agreement, a \$60,000-a-year consulting agreement, to do work on immunology. So, what your fellow was told does not seem to square with what the subcommittee was told. We will follow that up as well.

But we have a vote coming up, so why do we not say that we are going to recess for 10 minutes, and come back and get the rest of our witnesses.

I hope that we can get some questions in, Dr. Wagner. I am sure that this is a problem for you.

Dr. WAGNER. I am here until the end.

Chairman WYDEN. We are anxious to work closely with you.

[Recess.]

Chairman WYDEN. The subcommittee will come to order. We are on a very tight schedule today, let us proceed now to Mr. Wells. I appreciate everybody's patience. If you would take 5 minutes or so, Mr. Wells, and summarize your principal concerns, that would be very helpful.

Mr. WELLS. Thank you, Mr. Chairman. I would like to take one second to introduce my colleague, Mr. Lowell Mininger, who is our assistant director and who managed the investigative audit work that we are talking about today.

Chairman WYDEN. You are welcome as well.

TESTIMONY OF JIM WELLS, ASSOCIATE DIRECTOR, ENERGY AND SCIENCE ISSUES, RESOURCES, COMMUNITY, AND ECONOMIC DEVELOPMENT DIVISION, U.S. GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY LOWELL MININGER, ASSISTANT DIRECTOR

Mr. WELLS. We are pleased to be here today to discuss the findings of our May 1992 report on Controlling Inappropriate Access to Federally Funded Research Results. Although I am from the South, I will try to speed up my presentation to give it here in 5 minutes.

Our report, which dealt with the university research grants awarded by NIH and the National Science Foundation, basically examined the growing interactions between the universities and private industry. We discussed the increased potential for conflicts of interest that might give a particular company inappropriate access to and, therefore, an unfair advantage in commercializing the results of federally funded research.

The same kind of concern over conflicts of interest would also equally apply to a nonprofit research institute that is receiving substantial funding from the Government, such as the Scripps Research Institute that this hearing is focusing on.

This hearing is looking into the business relationships between the recipients of Federal research grants and companies intent on commercializing the discoveries and particularly the new 10 year, \$300-million agreement between Scripps and Sandoz, a pharmaceutical corporation, a private drug firm.

While we have not seen this agreement, nor was it signed during the May timeframe of our report, we did understand that NIH learned about it only after it was completed and announced in December 1992, which Dr. Healy addressed this morning.

In summary, Mr. Chairman, we believe that as a general principle the public interest is better served if the Government ensures that appropriate controls and safeguards are in place governing who gets the access to, and ultimately will benefit from, the results of federally funded research.

In this regard, our report recommended that NIH and the National Science Foundation basically require that their grantees have procedures in place to effectively manage these potential conflicts of interest, such as by requiring that the investigators or other key personnel disclose any outside interests as a part of any grant award process that they were involved in.

Similarly, we believe that it is important that the Government at least be consulted about any major multimillion dollar agreement that a university, a hospital, or other nonprofit research institute seeks to negotiate with a private company, if that institution is, in fact, receiving substantial Federal funding and the rights to commercialize resulting technology.

In terms of a perspective, as you know, the relationship of federally funded research to technology innovation has been transformed dramatically in the last 10 years since the 1980's, as new linkages have begun to be established among the academic community, industry, and the Federal Government.

The Bayh-Dole Act encourages nonprofit organizations and small businesses to commercialize inventions that they make with Federal funding by allowing them to elect to retain certain rights to such inventions. It has been quite successful.

They can transfer these rights by granting exclusive, what we call sole, or nonexclusive, generally available, licensees.

I think that definitionally appropriate access to federally funded research can include a couple of things. It can include granting an exclusive license to commercialize resulting technology to a business that cosponsors a research project.

It also can be granting an exclusive license to a business that did not fund the research but, in the eyes of the grantee, is considered best able to take that technology and commercialize it.

Third, I think encouraging the scientist who developed the technology to further develop and commercialize it by actually working with the licensee, we consider under Bayh-Dole as appropriate access to Federal research.

In contrast, inappropriate access could occur if a business that has not sponsored a research project obtains inside information about it, or gets favorable treatment in obtaining licensing rights to the resulting technology. Such inappropriate access could result from a financial or a personal relationship between the business and a member of or the entire nonprofit organization itself.

During our study, we found that the universities that we contacted were, in fact, licensing a substantial amount of funded technology. During 1989 and 1990, the 35 universities in our study had actually granted 197 exclusive licenses and 339 nonexclusive licenses, and earned approximately \$30 million in exclusive licenses and another \$53 million from nonexclusive licenses.

The typical licensees given exclusive rights to commercialize the results of federally funded research were basically small U.S. businesses; and most exclusive licensees were pharmaceutical, biotechnology, or other medical companies.

In our study, we found that relationships between the licensees and the universities are definitely becoming increasingly complex. The 35 universities reported to us that their scientists who developed the technologies for 61 exclusive licenses had, in fact, consult-

ing arrangements for or owned a substantial amount of stock in, or had other relationships with the licensees. Also, members of industrial liaison programs were granted exclusive licenses in four particular cases.

In 12 additional cases, companies that had long-term agreements with universities to fund general research received exclusive licenses for technologies that they did not directly cosponsor.

None of these relationships are necessarily inappropriate. In fact, in many cases, they are necessary for commercializing the technology that was to be applied. However, the potential does exist that exclusive rights to federally funded technology could be inappropriately granted because of undisclosed conflicts of interest or other relationships that the grantee may not be aware of.

Regarding your interest in the controls that exist over improper access to research, we found that NIH and the National Science Foundation basically lack strong controls. They have general guidelines only that basically rely on funding recipients to establish their own policies and procedures to resolve and report any potential conflicts of interest or other relationships.

Chairman WYDEN. Excuse me.

Mr. WELLS. Yes.

Chairman WYDEN. I want to make sure that I got that. You have found that generically there are not adequate controls in this area; and with respect to conflicts of interest, people are supposed to rat on themselves?

Mr. WELLS. Yes, sir, Mr. Chairman; basically, we found that the guidelines that existed from NIH consisted of one page. Of the 35 universities that we looked at, approximately 14 of them had only voluntary disclosure type policies. The other 21 had policies that required varying disclosures. But it was very scattered.

In response to the growing involvement of businesses in university research, NIH is considering alternatives to strengthening their guidelines for universities and other funding recipients to better and more uniformly control potential conflicts of interest in the conduct of research. Dr. Healy talked a little about those efforts today.

As you pointed out Mr. Chairman, they started in 1987. In 1989, after an earlier attempt, NIH actually had to withdraw the proposed guidelines, because the guidelines that were originally drafted became quite restrictive in terms of the interactions that might exist between the investigators and the biomedical industry. They are still working on those guidelines 3½ years later.

NIH is again attempting to promulgate regulations, and hopes to have those published in the Federal Register for public comment at some time in the future.

NIH's Associate Director for Intramural Affairs had indicated to us that the proposed rule that they are attempting to get through is likely to retain as strong a requirement as they can that all investigators and other key personnel involved in NIH research disclose certain types of outside interest before award is made and annually thereafter.

I think that our conversations with NIH recently indicate that they are considering whether to prohibit investigators or other key personnel in clinical drug trials from having any relationship

whatsoever with the business whose product is being tested. Dr. Healy talked to that issue this morning.

Quickly to our conclusions, Mr. Chairman. There is no doubt that the growing interactions between the universities and nonprofit institutes and private companies are increasing the potential for conflicts of interest. Requiring that investigators and other key personnel disclose certain types of outside interests as a part of a grant award process is definitely an essential first step for improving the grantee's management controls over future potential conflicts of interest.

With respect to the specific issues that this subcommittee is addressing today, we believe that it is equally important that a recipient of substantial Federal research funding, whether it be a university like the ones that we looked at, or a nonprofit research institute, notify and consult with NIH, or any other Federal agency for that matter, before entering into any such major agreement as the one that is being discussed today.

In this way, at a minimum, the Government can become aware of who gets access to and ultimately can benefit from the results of federally funded research, and then take appropriate actions to help ensure that the public interest is best protected.

Mr. Chairman, that concludes my remarks.

[Mr. Wells' statement may be found in the appendix.]

Chairman WYDEN. Mr. Wells, that was very helpful, and we thank you.

Dr. Etzkowitz, let us just move that microphone down to you. We are going to have to try to keep everybody to 5 minutes. We appreciate you coming.

TESTIMONY OF HENRY ETZKOWITZ, ASSOCIATE PROFESSOR OF SOCIOLOGY, STATE UNIVERSITY OF NEW YORK

Mr. Etzkowitz. Thank you, Mr. Chairman.

I have been asked to provide some background on the topic of academic/industry relations. I have done research on it for the past 10 years supported by grants from the National Science Foundation. I would like to summarize for you some of my findings about the changing role of the university, the relationship of large business to the university, and the relationship of small business, and the role that the Federal Government has taken.

First of all, we have seen a major change in the role of the university in our society. It started out as an institution to educate people. In the late nineteenth century, it began to become a significant producer of research.

In doing so, it developed along a different line than universities in the rest of the world where research was usually conducted in separate institutions apart from the university. A few universities in this country took on a third role. That of playing a role in introducing research into the economy and establishing new firms. MIT in particular, and Stanford.

This was taken note of by the Federal Government during the debate over reindustrialization during the Carter administration. At that point in time, the Federal Government decided that it could not take a direct role in developing new industry. So, what it

did instead was to turn over the rights to federally supported research to the universities. On the one hand, encouraged them to commercialize the research; and on the other, required them.

In effect, we put into place a hidden industrial policy in this country. We have had such a policy openly in agriculture with respect to support of military research and with respect to support of health research.

With the Bayh-Dole Act, we put it into effect with respect to the broader categories of research that have come out of NIH and NSF.

What has been the effect of this? As research funds have become more stringent, a new source of funds could flow into the university. On the one hand, from large companies through the chart which you have reproduced from our study. Andrew Webster and Henry Etzkowitz Academic Industry Relations: The Second Academic Relation? London Science Policy support Survey, 1991. But I think that even though these sums are large, these agreements are not the most important effect of Bayh-Dole and of internal developments within the university.

Because what we have developed in our universities are what I call quasifirms. Although the research is done by so-called individual investigators, they are not doing this as individuals. They have a group of graduate students, post-docs, and technicians working with them. They have virtually all of the attributes of a small business firm save for the profit motive.

At a few universities with a tradition of assisting the economy, the profit motive entered into their work as well. People like Vannevar Bush, as early as the 1920's, helped form the Raytheon Corp., and established a tradition of developing the economy in Massachusetts. Then this was transferred to Stanford and now, more recently, to the broader range of research universities.

So, it is the development of new firms out of federally supported research that is the most significant part of what has been happening.

Now in turning over the entire rights to the universities, the story did not end there. The universities then had to decide what to do. Only a few universities were equipped in 1980 to deal with patent rights. So, what eventually worked out was that offices were established in universities to license and transfer those rights. Faculty were encouraged to play a role, and they were given a share. Departments were given a share. The university retained a share. It was usually in thirds.

Firms were formed. If you were, as I have done, to do interviews in major biology departments, you will not find that it is a small proportion who have an equity interest or other financial arrangements with companies. You would be hard pressed to find anyone who does not at this point in time. Now you can get a low percentage if you look at the entire range of universities. But if you look at the leading universities where most of the research funds are concentrated, you will find a high proportion of scientists involved in these activities, especially in those areas such as molecular biology which have immediate financial and commercial implications.

What do I suggest from this? First of all, there are gaps in the process of forming small companies. The venture capital industry has virtually disappeared as a first stage funder of new companies.

So, academics and others have to rely on the Federal Government, getting grants from NIST and from the National Science Foundation. Only when you have such a grant, do you become credible then to the venture capital industry.

So, what I would suggest as a policy recommendation both to make our industrial policy explicit, which Bayh-Dole and Stevenson-Wydler started off, would be at this point for the Government to retain some of the earnings from its investment in research.

The universities are splitting it in thirds among the faculty, departments, and the university as an institution. Some share could reasonably be retained by the Federal Government. This could go to support a fund which would support the further commercialization of research from the university. The argument for public benefit would be the jobs and industries that are produced from this. It could also be used as a way to reduce the price of products that are produced from this research.

Finally, I would say that on the question of the various large agreements, that the large companies are increasingly dependent on university research supported by the Government. The universities have the ability to set stringent terms for access to that research. If the university does not want to have an extensive period of delay in publication, it can set the terms to be just a few months, and companies will accept it. That is what has happened in negotiations when universities take a tough position.

I would conclude by saying that we have gone through a transformation in this country, in which our universities have become a major driving engine within the economy. I think that is something that we want to promote. We also then have to recognize that if we now see a major purpose of a university as economic development, then it is hard to say that it is a conflict of interest if people within the university, as they are encouraged to by Federal law, gain financial benefits from that.

So, we also have to rethink the whole conflict of interest issue to see where it does or does not apply in light of the new purpose that we have put our universities to.

Thank you.

[Mr. Etzkowitz' statement may be found in the appendix.]

Chairman WYDEN. Thank you. That was very helpful and not testimony that we have heard before. We appreciate it.

Mr. Wells, let's begin with you. My understanding of the General Accounting Office opinion, is that while Dr. Healy and I have indicated that we hope that there are not a lot of other Scripps/Sandoz deals out there, you believe that the environment for these kinds of exploitive arrangements is really pretty fertile, do you not?

Mr. WELLS. Yes, sir; I think that we would have to say, based on our look at the procedures and policies that are in place at NIH today, that basically they do not give NIH the opportunity to know what is out there, evidenced by their most recent request letter, just going out a couple of weeks ago, asking for what information exists out there regarding existing agreements.

Chairman WYDEN. What do you think is behind this whole problem of getting these conflict of interest guidelines on line, Mr. Wells?

Mr. WELLS. It is a problem in a regulatory framework involving NIH, which has responsibility for issuing those guidelines. NIH has had great difficulty reaching internal consensus on its draft guidelines. It has taken a number of years, and they are still not out.

Chairman WYDEN. It has been what, 6 or 7 years in the process?

Mr. WELLS. I believe it started in 1987, sir.

Chairman WYDEN. Dr. Wagner, to the extent that Government funds go into pharmaceutical development, my sense is that you all believe that Government research and industry drug development are closely tied, and that this is a growing trend; is that correct?

Dr. WAGNER. Yes; it is. I think that Government is the main stay of the biomedical research establishment. To the extent that industry collaborates, they are piggybacking on that extensive Government infrastructure, both a physical infrastructure, a personnel infrastructure, and, of course, a training infrastructure.

Chairman WYDEN. I am sure that this is hard to quantify, but what is your best sense of the amount of Government subsidized research that goes to the drug industry?

Dr. WAGNER. I am going to let Dr. Gluck answer that. He is the principal senior analyst.

Chairman WYDEN. Dr. Gluck.

Dr. GLUCK. Thank you. It is difficult to measure that in the aggregate. There are no real centralized data sources in which to estimate either the Government's or the industry's contributions, particularly with respect to the amount that goes into universities.

It is possible, however, to look at the case of individual drugs. We did that in the case of Ceredase, which you are familiar with from past work that the committee has done.

We know from our investigation there that NIH, the Federal Government's own laboratory, was responsible for the discovery of that drug, as well as the testing in the laboratory and in individuals.

Beyond that one case, we also know that there are certain therapeutic areas where the Government itself, in its own research labs, possesses the expertise in developing and testing drugs in humans, the type of expertise that you might otherwise expect to find in industrial labs for other types of drugs. For some types of drugs, like those for cancer and AIDS, that expertise actually resides in the Government.

Chairman WYDEN. Mr. Nader, a question for you. We have heard in our inquiry, that Bristol-Meyers, for example, made this argument constantly as we were going into the Taxol issue, that if there were efforts to try to better monitor these kinds of deals and ensure that kind of accountability that you and several of our witnesses have been talking about, the drug companies, in effect, would just walk away from the whole process of trying to promote new products, and that we would not have cures for these terrible illnesses.

They essentially assert that any effort to ensure that kind of accountability that you are talking about and that I have been interested in, would somehow kill the goose, in their words, that is laying the golden egg of new cures in medicine.

What would be your response to that kind of argument?

Mr. NADER. Well, usually, the drug companies in their promotional literature would say that they need exclusive rights to the drugs, because they are putting so much money at risk in researching the invention of these drugs. That process does not apply where the taxpayer is funding the research right through the clinical trials, and then through NIH, in effect giving away for marketing purposes the drug to a designated drug company.

So, Bristol-Meyers needs to be asked, you did not spend any money researching Taxol, you did not spend any money developing the clinical data, you are not going to spend any money paying for future access to clinical data generated by NIH, so why should you have this kind of exclusive right to create a monopoly and, therefore, price the drug at a monopoly level, which is going to be around \$10,000 per completed treatment or per year per patient.

I think that distinction has to be made. These drug companies do not have any money at risk in developing the drug. They are purely marketing conduits. That should be open to competition that, as the generic drug industry has shown, can compellingly reduce prices for the patient and the consumer.

Chairman WYDEN. Well, we want to work with you and your Taxpayer Assets Project, particularly on this issue. Vis-a-vis what these companies do as it relates to getting the drug to market: Are they, in effect, just marketing distribution operations, or are they contributing intellectual property.

We had the folks from Bristol-Meyers at the Taxol hearing. Dr. Broder from NCI wrote me that Taxol was discovered and developed by the Federal Government. Not partially developed, but discovered and developed. The folks from Bristol-Meyers came and said that the American people ought to be happy, and they held up this box that they said was full of Taxol, and that it was going to be distributed to the women of America. What we really wanted to know was what was Bristol-Meyers doing other than putting the thing in a box.

Mr. NADER. They do try to put a color of R&D attached crustacean like to the NIH ship of research. Burroughs-Wellcome, of course, has been very adept at that with the AZT drug, where its clinical applications for AIDS was developed by NIH funds and scientists.

Are you aware of the markup that Bristol-Meyers engaged in? They bought the manufactured product of Taxol from the manufacture for a unit of one. The retail markup was almost 19-fold, I believe. That gives you an idea of the level of profit that is involved.

Chairman WYDEN. We are going to keep the heat on that one.

Mr. NADER. Especially as the drug becomes more applicable to other cancers.

Chairman WYDEN. Dr. Etzkowitz, a question for you. I understand that you have looked at an agreement between Monsanto/Washington University and have some questions there about the ramifications on the impact of faculty and their ability to engage in independent research and other questions; is that correct?

Mr. ETZKOWITZ. Yes; in that agreement, the terms were structured as much as possible on the NIH/NSF format of peer reviewed research, a joint committee of faculty and industry scientists. So, you could apply for a grant so to speak, but within an

area set by the company. It was not as broad ranging as a NIH research program would be.

But even though I think that this conforms as much as possible to academic procedures, I think that the most interesting thing in terms of the Monsanto agreements is to note that they have all ended. The one at Harvard, the one at Washington University, and, most recently, the one at Oxford.

We should ask why is this the case, and why did Johnson & Johnson leave Scripps, and why did Sandoz move in? I think that the answer has to do with the time perspective of American corporations in terms of research.

One thing that these agreements are potentially good for is to introduce a longer time perspective on research both to the companies and to connect them to university-supported research.

But companies such as Monsanto have withdrawn from these agreements, and have often been replaced by foreign companies that have longer time perspectives. It has not only been relationships to the universities but Hoffman LaRoche, as you well know, has also come in and become the financial backer of Genentech at a point when the company was in financial trouble. When this company came in, they were told to keep their long-term research projects going.

So, in interviewing scientists and people who run centers at American universities, what I find is that, often at the behest of Federal requirements to introduce industry into the university in centers, access is offered to companies. But American companies have difficulty in taking advantage of that access. It is difficult for scientists to leave their company. But foreign companies support that kind of long-term access.

So, shorter term visits are set up to relate to the American companies, whereas the foreign companies take advantage of these longer term relationships.

Chairman WYDEN. One last question, because time is short.

With respect to GAO, I know that you all have not seen the actual contract between Scripps and Sandoz, but you have some views about the possible implications on small businesses and other interested parties with this kind of an agreement. Mr. Wells.

Mr. WELLS. Yes, sir; as you mentioned, we have not had an opportunity to look at the specific provisions in the Scripps and Sandoz agreement. But the apparent magnitude of this kind of arrangement would certainly seem to have a lot of possible implications. In particular, by giving one company an incentive to develop potential new products from research, it certainly would restrict access to research by others.

I think that it is also fair to say that it would tend to restrict a normal free exchange, which has been viewed as so important between the scientists in the laboratories and in the private sector.

I think that another concern definitely to small business would be that this type of an arrangement may create somewhat of a precedent for similar types of agreements with nonprofit organizations, and thus, basically limiting the number that are out there that would be available to work with other small businesses. Those are valid concerns.

Chairman WYDEN. This is not exactly what was envisaged by Bayh-Dole, was it?

Mr. WELLS. No, sir.

Chairman WYDEN. You all have been very helpful. If time allowed, we would have a lot more questions. But we are going to be working closely with you in the days ahead. We thank you for your patience and cooperation.

Our next witness is Dr. Ernest Beutler, chairman, Department of Molecular Medicine, Scripps Research Institute, La Jolla.

Doctor, we welcome you. It is the practice of our subcommittee to swear all of the witnesses who come before the panel. I know that you are off doing very important science for the most part, and do not spend a lot of time coming around to congressional hearings.

But I do need to ask you, do you have any objection to being sworn as a witness?

Dr. BEUTLER. No.

Chairman WYDEN. Please rise and raise your right hand.

[Witness sworn.]

Chairman WYDEN. Doctor, we will put your prepared statement into the record in its entirety. If you could take a few minutes or so to talk to us and tell us your views, that would be helpful.

I again want to thank my colleague from San Diego, Congresswoman Schenk, who has helped so much in our involvement and work with you. Please proceed.

TESTIMONY OF ERNEST BEUTLER, CHAIRMAN, DEPARTMENT OF MOLECULAR AND EXPERIMENTAL MEDICINE, THE SCRIPPS RESEARCH INSTITUTE

Dr. BEUTLER. Good morning, or good afternoon now.

My name is Ernie Beutler, and I serve as the chairman of the Department of Molecular and Experimental Medicine at the Scripps Research Institute. I am a physician scientist. I specialize in blood diseases and genetics. I am a member of the National Academy of Sciences and the former president of the American Society of Hematology. I served on numerous NIH and FDA advisory committees as well as some industrial advisory committees.

When I heard Dr. Healy testify this morning, I wondered whether she was talking about the institution at which I have worked for the last 14 years. She raised some very serious problems. As a matter of fact, if these problems really existed, I would not be sitting here, and I would not be working at Scripps.

At this time, I would like to address just a couple of the problems that she raised. First of all, and a very serious one, is her suggestion that under the proposed agreement the Joint Research Council would control all of the research that was being done at Scripps, and that this council was controlled by Sandoz.

As a matter of fact, I am a member of the Joint Research Council. It consists of equal numbers of scientists from Sandoz and from Scripps. There are no administrative personnel on it. The contract, which I suppose that her counsel did not read sufficiently carefully, states specifically,

It is recognized that TSRI is an independent research institute which is controlled and directed by its board of trustees and management.

Dr. BEUTLER. I might say that the board of trustees has 10 members.

That TSRI controls and directs its research and related affairs. That the Joint Scientific Council may not control or direct TSRI research and related affairs. The activities of the Joint Scientific Council are not intended to and shall not empower the Joint Scientific Council to control or direct TSRI research and related affairs.

Dr. BEUTLER. I do not really know what could be more specific.

Now a second matter about which she was concerned was the assumption of research supported by NIH by Sandoz. If they could take a research project that NIH had financed, that they could take it away to Sandoz. The fact is that they cannot. The only research projects that they are allowed to take away from Scripps are ones that they have funded under a specific funding agreement. The purpose of that arrangement was when a research project got to the point where it was no longer research but became development and implementation, that it would go to the firm.

Dr. Healy expressed concern that any clinical studies would be done at Scripps at the behest of Sandoz. Now, as I am sure she knows, NIH regulations require that every institution doing clinical research has what is known as an IRB or an Institutional Review Board.

The Institutional Review Board at Scripps is not at the Research Institute at all. It is at the clinic, which is not a part of our corporation, and which obtains no support from Sandoz. It is comprised of independent physicians and outside people.

She expressed concern about the fact that people who have a financial interest in having a product succeed let us say might be the very ones that test it. I absolutely agree with her. There should be rules to prevent this. As a matter of fact, we do not allow this to happen at Scripps.

Finally, I might state that in the written testimony on page 13 that there is a quote from the agreement, which states that Sandoz expressly acknowledges that its rights and obligations pursuant to this agreement with respect to Scripps technology, et cetera, are subject to Scripps obligations and rights of the U.S. Government, if any which arise or result in Scripps receipt of research support from the U.S. Government.

So, it is very clear from the agreement that whatever the rules are, Scripps is going to follow them, and Sandoz is going to let us follow them.

For the last 10 years, we have been in an agreement with Johnson & Johnson which is substantially identical to the agreement that is being contemplated, but has not yet been consummated with Sandoz.

I cannot speak to what life for a medical scientist would be like under the Sandoz agreement. I would be very frightened about life under that agreement, if it were as Dr. Healy had interpreted it. I am reassured by what I have seen in the actual contract.

I would like to provide you with just one concrete example of how implementation of the Bayh-Dole Act under the Johnson & Johnson agreement has worked. Our experience with 2-CDA, a product just licensed by the FDA on March 2d for a rare form of leukemia, is a good case in point.

This drug was developed in the late 1970's by Dennis Carson, an extraordinarily talented physician/scientist, who had recently begun his career in my department. He and I began treating patients with leukemia with this compound made in his laboratory at Scripps in 1982. We were immediately impressed with its potential.

However, when I contacted our patent counsel regarding a use patent on this compound, I was informed that because Dr. Carson had published a paper on the treatment of mouse leukemia 3 years before, we could not obtain patent protection.

In the 1970's, before an institute such as ours were encouraged to maintain arrangements with industrial partners, our faculty gave no thought whatsoever to such matters as patents. This lack of foresight in the case of 2-CDA proved to be nearly disastrous.

As you might imagine, industry had very little interest in investing in a drug for which they had no patent protection, a situation which I might say is somewhat akin to the nonexclusive licensing of drugs that has recently been proposed as one solution to the drug price problem.

It required several years, the availability of orphan drug status, and the evolution of our partnership with J&J for Dr. Carson and me to persuade Johnson & Johnson to undertake the expense of time consuming and admittedly risky task of developing 2-CDA to a drug approved by the FDA.

The initial lack of involvement by industry in this case resulted in several years delay in making 2-CDA available to patients. But ultimately, the results have been very gratifying. 2-CDA may be a cure for hairy cell leukemia. It is certainly the best treatment available. If we had not had access to an industrial partner to develop 2-CDA, it would still be a curiosity, an experimental treatment available in only a few centers. Now it can be used by physicians everywhere to treat their patients.

Finally, I would like to conclude, since I do want to keep my comments as short as possible to give you time to explore any of these areas that you wish, that my academic freedom is not abridged at Scripps as a result of the corporate relationship that we have had for the last 10 years.

I have never been asked to undertake any research project. No one in my department has ever been asked to undertake a research project. Indeed, I would not be willing to work at an institution where I was not able to maintain my full academic freedom. I think that is true for most of my colleagues.

I hope that these thoughts are helpful, and I would be glad to respond to any questions.

[Dr. Beutler's statement, with attachments, may be found in the appendix.]

Chairman WYDEN. Doctor, thank you. Let me first say that we are aware of your very significant scientific contributions, and appreciate their magnitude and scope. I always want to make sure that I am asking the right questions of the right person. You are a scientist, who is neither a lawyer nor manager.

Have you actually read this contract?

Dr. BEUTLER. I have read portions of the contract, and I have read a summary of the contract.

Chairman WYDEN. For example, were you aware of some of these provisions, as Dr. Healy had testified, in terms of Scripps agreeing to help Sandoz get a waiver around the U.S. manufacturing requirement?

Dr. BEUTLER. No.

Chairman WYDEN. Does that trouble you?

Dr. BEUTLER. I think that is an area in which I am really not qualified to comment.

Chairman WYDEN. My concern, and as I say I do not want to ask you about matters outside of your province, of course, involves this specific contract. We are looking at the specific contract because of its magnitude, and we are talking about a potential \$1 billion in taxpayer funds over the next few years going out the door in a fashion that Dr. Healy has characterized as having a significant restriction on the free flow of information.

There are areas certainly that are subjects for debate. I gather that you think what Scripps has given up is something akin to an option to take an option. But as I look at Sandoz press releases, they are very specific about what they think they have got, and they are a pretty "bottom line" oriented corporation. They think, as they say in their press release, that they get first rights to Scripps medical discoveries.

Dr. BEUTLER. Right. That is exactly the kind of arrangement that we had with Johnson & Johnson. As a working scientist and physician, and also having some considerable administrative responsibility in the organization, I can tell you that contract worked out very well for us. I must say that it probably worked out less well for Johnson & Johnson. Because 2-CDA, which I have mentioned to you here, is the very first therapeutic product that they have obtained after investing more than \$125 million in Scripps. This represents \$125 million of research money that we were able to use to leverage the money that we were getting from NIH, not really the other way around.

Chairman WYDEN. Did Johnson & Johnson commercialize about 85 technologies or therapies licensed from the particular lab where you were?

Dr. BEUTLER. I think that there are a few minor diagnostic tests that they have commercialized. The only therapeutic agent that they have commercialized is 2-chlorodeoxyadenosine which is the drug that I worked on with Dr. Carson.

Chairman WYDEN. But you are not aware of the fact that they have licensed 85 technologies for the lab?

Dr. BEUTLER. I am aware of the fact that they have licensed many technologies. But there is a big difference between licensing a technology and making money from it. They have made very little money from this contract. This contract has been very much to the advantage of the American taxpayer in the sense that a lot of money went to Scripps for research, and very little product went to Johnson & Johnson for sale.

Chairman WYDEN. We are going to look into that. It is hard to figure out why a major corporation like Johnson & Johnson would look to license these things other than the fact that they were very lucrative commercial opportunities. Possibly there are other reasons that you would suggest.

Let me just ask one other question. My understanding is that the Sandoz money and the NIH money at Scripps is commingled into one overall pot, if you will.

Dr. BEUTLER. It could not possibly be.

Chairman WYDEN. It is not?

Dr. BEUTLER. No; it is not.

Chairman WYDEN. This is a matter that we will pursue with our friends at NIH, because they seem to be of a different opinion.

Dr. BEUTLER. Would you like me to respond to that in greater detail?

Chairman WYDEN. Sure.

Dr. BEUTLER. It may very well be that there are projects that are supported both by Sandoz general funding and by NIH funding. But the funds are certainly not commingled. Every grant is kept in a grant account, and we know exactly what has been spent from it and how much is left.

Chairman WYDEN. Well, my understanding from the National Institutes of Health is different.

Dr. BEUTLER. We have also received no money from Sandoz, because the contract has not been consummated.

Chairman WYDEN. My understanding from the folks that we talked to at the National Institutes of Health is that these funds have been commingled. You have now told us that certain projects have funds that are commingled.

Dr. BEUTLER. No, Mr. Wyden; I said no funds were commingled. I said there are some projects that are pursued with more than one source of funding, but the funds are never commingled. Every grant fund is kept in specific categories of how much has been spent for salaries, and how much has been spent for supplies from that grant for that project.

Moreover, as I just said, there are no Sandoz funds. So, it is strange to see how the NIH could say that they have been commingled.

Chairman WYDEN. Well, a fine difference. The Scripps/Sandoz agreement, of course, is supposed to start in 1997, I guess. They are making the argument that you cannot have two exclusive arrangements at the same time.

Dr. BEUTLER. You cannot commingle funds that do not exist.

Chairman WYDEN. But based on what we have heard from the people at NIH, you certainly can figure out a way to employ them for more than one project in a way that certainly blurs the lines. We will follow up with the National Institutes of Health on this matter.

Let me ask my friend from San Diego if she would like to ask any questions of her constituent?

Ms. SCHENK. Thank you, Mr. Chairman. Again, I greatly appreciate your courtesy in this matter. I do have a couple of very brief questions. Since you, Mr. Chairman, asked most of the questions that I would have asked.

First, Dr. Beutler, going back to the point that you were just making, is there a practical difference between commingling of account and having dual funding?

Dr. BEUTLER. Yes; I think that there are two different matters. Commingling of accounts would mean to me putting all of the

money into one account, and then spending from that account for whatever you need for that project. Having dual funding might mean that you have a project going on in which you have support from NIH. NIH customarily cuts back support by 16 percent or so from the actual authorized amount.

If there is a technician working on that project, and you do not have enough money to pay him or her, so you use money from general funding, let's say in this case from J&J. It could not be from Sandoz, because there is no money. So, that person might be paid out of Johnson & Johnson. The rest of the people might be paid out of a grant. But the funds are not commingled.

Ms. SCHENK. But the end product, the research, who owns it?

Dr. BEUTLER. The end product is supported by both.

Ms. SCHENK. But who has the rights to it?

Dr. BEUTLER. Well, the Institute has the rights to it under current law. We just obey the law the way that it is.

Ms. SCHENK. As I said, just a couple of quick questions.

Does Scripps, as far as you know, have any procedures to prevent conflicts of interest by its employees?

Dr. BEUTLER. Yes; we do. All consulting agreements have to be reported to our industrial affairs office. They are inspected for possible conflict of interest. If a conflict of interest is perceived at the management level, for example negotiating an agreement with a firm, then this is reported to the board of trustees. If the person who is involved is on the board of trustees, then he or she would not participate in making the decision.

Ms. SCHENK. Do they ever go the next step perhaps to consult the NIH about potential conflicts?

Dr. BEUTLER. I do not know whether they have or not, Ms. Schenk.

Ms. SCHENK. One last question. Do you feel that institutes like Scripps need clearer definitions and guidelines within the law in these areas?

Dr. BEUTLER. That is a very difficult question to answer. I think that there is not any question that we always have and we always will abide by any guidelines that the Federal Government, the NIH, and State governments set up. Obviously, as I think Mr. Kim pointed out in his opening remarks, we are all caught in a web of regulation. That is true not only for small business, but also for large business.

So, if there were another layer of administrative review for everything that is done, it would just make science move more slowly. I think that it is obviously up to the NIH and for this subcommittee to decide whether there is a necessity for additional regulation.

But I think that the perception that Dr. Healy gave you that such regulation is badly needed is based on an early, and I think, a misreading of a contract. It might have been a little bit more productive if she and her attorneys had consulted with Scripps to obtain clarification of some of the points that she brought up. I think that probably that they would have felt much more satisfied about the contract once they understood what its implications were.

Ms. SCHENK. My question was not about the need for more administration here, but the need on the part of institutions such as yours for clearer guidelines.

You feel that the guidelines are pretty clear, and that you understand them?

Dr. BEUTLER. The guidelines, as far as I understand them, are pretty clear.

Ms. SCHENK. That is all that I have. Again, thank you.

Thank you, Mr. Chairman.

Chairman WYDEN. I thank my colleague.

I want to recognize the minority now for a minute, and then I am going to have to get out of the door.

But let me just tell you, Dr. Beutler, you always want to ask the right things and say the right thing to the right witness. My understanding is that your expertise is in the scientific area, and it is a very significant contribution that you have made. But I hope that you and your associates will also put yourselves in the shoes of the taxpayer, because I think what the taxpayer sees is \$1 billion going out the door over the next 10 years, or \$100 million per year. The Federal Government, based on the articles that we read in the San Diego Union, not only does not approve it, but the Federal Government according to your own press people, does not even know anything about it.

It seems to me, at least what I hear at home, that we need a lot more accountability of over \$1 billion, than to hope that maybe after the fact you read about it in the newspaper.

I say that just so you know that we do not want to diminish the scientific contributions that you and your associates have made. I have tried to take special note of them. But I hope that this will also be looked at in the eyes of the taxpayer, who I think wants a lot more accountability of over \$1 billion than what we read in the San Diego Union, where the Federal Government did not even know about this particular transaction, let alone approve it.

Dr. BEUTLER. Well, Mr. Wyden, I am sure that a man of your accomplishments and sophistication does not believe everything that they read in the newspapers.

Chairman WYDEN. It was your press person.

Dr. BEUTLER. No; not our press person.

Chairman WYDEN. Yes; Mr. Beers. Do you want me to read it to you? Mr. Beers of Scripps was quoted in the newspaper, I almost remember it verbatim. There was no formal contact with the National Institutes of Health on this billion dollar deal. People in the Federal Government read about it in the newspaper. That is almost a verbatim account of what your press people said.

Let me recognize the minority, and move on. I appreciate their cooperation.

Mr. LEHMAN. I appreciate you giving us the opportunity to ask questions. Congressman Combest wanted to ask two simple questions. One is along the lines that the chairman just asked about, taxpayer benefits.

What are, in your opinion, the taxpayer benefits from such agreements as between Sandoz and Scripps?

Dr. BEUTLER. Well, I took at this as leverage, which is in favor of the taxpayer. Instead of getting a billion dollars worth of research,

the taxpayer is getting let's say \$1.3 billion worth of research. I think that the billion figure itself is not really quite fair. Because it implies that all of the research done at Scripps not only has scientific value but commercial value. In reality, I think that there is a rather small subset of the work that is being done at Scripps which has any commercial potential.

Most of the work that we do is very basic. It involves cloning genes that are of interest to us. It includes trying to understand life processes better. Things that maybe can be important in the understanding of cancer 10 or 20 years from now, but that really do not have any commercial value.

So, when I hear that figure of a billion dollars of taxpayer money being used commercially, I consider that to be a little bit inaccurate. Because I think that it may be more like a \$100 or \$200 million figure, which is being leveraged up by the funds that are being contributed by the pharmaceutical industry.

As I pointed out to Mr. Wyden, the experience of Johnson & Johnson shows that the taxpayers got let's say, I cannot add it up right now, but let's say they got \$500 million worth of research for \$350 million. So, I think that the taxpayer really benefits not only in this financial sense, but also in the fact that these kinds of alliances, however they are structured, give us the opportunity to translate what we do in the laboratory where it can come to the patient.

The regulation of drug development is so complicated these days. The requirements that the FDA has to impose in order to maintain drug safety are so complex that there is no way that an institution like ours can bring a drug to market. This task of selecting the right labels for the bottles, the right glass for the bottles, the right stability testing, and so forth. This has to be done by industry. If it is not done by industry, then the taxpayer never gets the benefit at all.

Mr. LEHMAN. I just have one last question, Mr. Chairman.

One point that seems to be in question here is Dr. Healy mentioned that the agreement between Sandoz and Scripps is considerably different than other similar agreements.

Is it your opinion that it is not?

Dr. BEUTLER. My opinion is that it is probably not. But I have not read the other agreements. I believe that Dr. Healy has not read the other agreements. So, it is really premature to discuss its relationship.

As Mr. Wyden very wisely pointed out, I am not a lawyer, and I have not read the whole agreement. As I understand it, and I have talked to people from Sandoz and our own administrative staff, I think it is very similar in outline to the Johnson & Johnson agreement.

Mr. LEHMAN. I appreciate that.

Thank you, Mr. Chairman.

Chairman WYDEN. Dr. Beutler, again, we very much appreciate your coming. My guess is that we probably did not have the person who could have filled us in on a lot of the legal aspects of this in which we are interested. But it would be wholly unfair to blame you for that. We appreciate your scientific contributions. We wish to see those scientific contributions go forward.

I am a supporter of collaborative research. I wrote one of the technology transfer laws that, in fact, promotes technology transfer by small business. But we must also be attentive to the interest of taxpayers and consumers. I gather that you are concerned about that as well.

Dr. BEUTLER. Absolutely.

Chairman WYDEN. We will want to talk to you and your associates in the days ahead.

The subcommittee is adjourned.

[Whereupon, at 12:55 p.m., the subcommittee was adjourned, subject to the call of the Chair.]

APPENDIX

OPENING STATEMENT
REP. RON WYDEN

DRUG DEVELOPMENT DEALS BETWEEN TAX-SUPPORTED LABS AND
PHARMACEUTICAL MANUFACTURERS:
WHO OWNS THE RESULTS? HOW SHOULD THEY BE PRICED?

BEFORE THE SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES AND TECHNOLOGY

March 11, 1993

Today, the Subcommittee on Regulation, Business Opportunities and Technology continues its two-year-long inquiry of the pricing of drugs and medical devices which are the result of cooperation between taxpayer-supported, non-profit research labs, and the pharmaceutical industry.

The potential importance to the nation's public health of this medical research collaboration is not in dispute. From these projects flow life-enhancing treatments for cancer, medications for cardiovascular disease and cures for diseases and conditions that formerly meant death or a lifetime of disability for many of our fellow citizens.

But this collaboration, over time, also has cemented the economic foundation of a very large, very profitable industry. On a continuing and increasing basis, the pharmaceutical industry mines a motherlode of valuable medical discoveries from a lab system federal taxpayers support with almost \$10 billion per year. Of these billions, three dollars of every four go to a university or independent lab.

The federal administrators supervising this system appear to have little control over the prices charged by private drug manufacturers who are their partners in either project specific, or broad based research ventures. This system results in the commercialization of drugs discovered and developed in federal labs, and then priced out-of-sight by the pharmaceutical industry.

Today, we turn to the experience of private, non-profit research labs, some in universities and some independent, which receive a significant if not majority portion of their annual operating budget through federal grants. In 1991, for example, the top 25 independent and university labs received over \$5 billion in federal awards, mostly through NIH grants.

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Of special interest to the subcommittee are the instances where private, non-profit research institutes receiving the bulk of their financial support from the federal government sign exclusive technology transfer agreements with private drug companies. Such agreements by definition can be most detrimental to small business, because they create monopolies dominated by very large, multinational pharmaceutical corporations that reduce marketplace competition.

The subcommittee intends to use as case study, today, a major, 10-year-long agreement entered into by the Sandoz Corporation of Basel, Switzerland, and the Scripps Research Institute of La Jolla, California. Scripps gets most of its operating funds, almost \$100 million per year, from the federal Treasury. It has signed an exclusive technology transfer arrangement with Sandoz, which will supersede an already existing exclusive arrangement between Scripps and Johnson and Johnson Corp. As a result of its agreement, Sandoz will have access to a projected \$1 billion worth of federally supported research.

A billion dollars is obviously a lot of taxpayer money. One would hope that government would scrutinize how it was being spent. But in this case, the key government agency was neither informed nor consulted about the deal. We have a situation where the labs and the drug companies romance one another, cut sweetheart agreements and the taxpayer gets jilted.

Here's one for Ripley: This seems to be standard operating procedure.

The Scripps case raises many troubling issues. There's evidence that at least some federally supported research institutions believe they are under no legal obligation to show the government the agreements they have entered into with private drug companies.

The federal government appears to be bolstering the profit margin of a large foreign corporation. Meanwhile, we freeze competition, decrease market access to small companies and probably encourage higher drug prices for consumers.

In addition, it appears the federal government has turned a blind eye toward conflict-of-interest risks involving key administrators or researchers at these tax-exempt, federally subsidized institutions. Drug companies may reward these individuals with consulting contracts and equity ownership incentives. Clearly, these sweetheart deals can bias decisions made by these key lab personnel regarding (1) the research direction taken by the federally subsidized labs, and (2) who gets to market the results.

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Yet, for years the Department of Health and Human Services and the Bush White House, responding to pressure from the drug industry, squelched a package of conflict-of-interest regulations designed to discourage misuse of federal grants. This is simply unacceptable. And it has fueled an atmosphere of troubling entrepreneurship among insiders at these labs.

Because of our concern with potential conflicts of interest, we will examine evidence that a key administrator at Scripps also has a lucrative consulting contract with the drug manufacturer who enjoys an exclusive technology transfer agreement with the lab. Does this arrangement bear on research decisions at the lab? Is the public interest protected?

For the record, Johnson and Johnson, and Sandoz, have declined the subcommittee's invitation to testify, although both have submitted written statements to the hearing record at the subcommittee's request. Without objection, those statements will be included in today's hearing record.

The Chair notes that the NIH, at our request, is looking beyond the Scripps-Sandoz, and Scripps-Johnson and Johnson deals. NIH is trying to define the extent of similar arrangements throughout its grantee community. More than 100 research institutions receiving NIH money are being surveyed by the NIH.

Dr. Bernadine Healy, the NIH director, will testify today on the progress of her inquiry, as well as on the specifics of the Scripps-Sandoz and Scripps-Johnson and Johnson collaborations.

Beyond the question of pricing of products, this deal raises many questions which are of critical concern to scientists, the government and the average taxpayer.

How will this deal impact normal interchange between scientists within and outside of Scripps, and how will that affect the course of groundbreaking science? Will a Scripps scientist whose bread is not only buttered but paid for by Sandoz be barred from speaking to a colleague at the University of Oregon, or at Georgetown?

What kind of controls are in place to prevent an unscrupulous administrator from selling access to his laboratory for what amounts to a professional or financial gain?

Also, do our drug companies have the same kind of access to public supported labs in foreign countries that foreign companies appear to have to ours?

Page Four

In the Chair's view, government acquiescence to arguments by federally supported research institutions that drug company collaboration deals should remain secret would be irresponsible in the extreme. Continued refusal to share this information should be the grounds for divorce -- federal grant money should be withheld.

Finally, the Chair notes that there are substantial questions as to whether the Scripps deals comply with the Bayh-Dole Act, which is the principal federal technology transfer law.

The Chair will take special interest in this issue and intends to specifically examine the impact of these deals on small business, and the encouragement of monopolistic pricing practices on important new drugs.

LARRY COMBEST
19TH DISTRICT TEXAS

COMMITTEE ON AGRICULTURE
COMMITTEE ON SMALL BUSINESS
PERMANENT SELECT COMMITTEE
ON INTELLIGENCE

Room 1511
LONGWORTH HOUSE OFFICE BUILDING
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Congress of the United States House of Representatives

OPENING STATEMENT OF REPRESENTATIVE LARRY COMBEST

HEARING BEFORE THE HOUSE SUBCOMMITTEE ON
REGULATION, BUSINESS OPPORTUNITIES, AND TECHNOLOGY

MARCH 11, 1993

THANK YOU, MR. CHAIRMAN. I WANT TO FIRST SAY THAT I LOOK FORWARD TO WORKING WITH YOU IN A BIPARTISAN MANNER ON THE MANY REAL PROBLEMS FACING THE NATIONS 20 MILLION SMALL BUSINESSES.

I BELIEVE THAT THERE ARE SERIOUS POLICY QUESTIONS THAT NEED TO BE ADDRESSED IN CONNECTION WITH COLLABORATIVE BIOMEDICAL RESEARCH AGREEMENTS BETWEEN PRIVATE RESEARCH INSTITUTIONS AND THEIR INDUSTRIAL PARTNERS. HOWEVER, I ALSO HAVE SOME CONCERNS AS TO JUST WHY THE SUBCOMMITTEE IS FOCUSING ON ONLY TWO PLAYERS IN THIS AREA--HUNDREDS OF SUCH AGREEMENTS HAVE EXISTED SINCE CONGRESS ENACTED THE BAYH-DOLE ACT OF 1980.

BECAUSE OF PAST REQUESTS FROM THE SUBCOMMITTEE, THE NATIONAL INSTITUTES OF HEALTH (NIH), HAS ASKED 103 UNIVERSITIES AND PRIVATE RESEARCH INSTITUTES FOR ALL INFORMATION THAT MAY HAVE BEEN COLLECTED ABOUT INSTITUTIONS RECEIVING SIGNIFICANT FEDERAL FUNDING. I AM CONCERNED THAT BY FOCUSING ON ONLY ONE AGREEMENT, THE SANDOZ-SCRIPPS AGREEMENT, THERE IS AN APPEARANCE OF IMPROPRIETY WHICH MAY NOT EXIST.

FURTHERMORE, MR. CHAIRMAN, IT IS MY UNDERSTANDING THAT NIH HAS RECEIVED LITTLE OR NO RESPONSE FROM THE MANY INSTITUTIONS CONTACTED. WHILE NIH HAS RECEIVED SOME INFORMATION ON THE AGREEMENT BETWEEN SCRIPPS AND SANDOZ MY UNDERSTANDING IS THAT FEW OTHERS WHO ARE SCHEDULED TO TESTIFY HERE TODAY HAVE SEEN THE AGREEMENT IN QUESTION. I ALSO UNDERSTAND THAT THIS AGREEMENT HAS NOT BEEN COMPLETELY FINALIZED AND WOULD NOT GO INTO EFFECT FOR YEARS.

MR. CHAIRMAN THE BIOTECHNOLOGY FIELD IS ONE OF THE SHINING STARS IN OUR ECONOMY. SOME FOLKS AT THIS HEARING MAY TRY TO CONTRADICT THAT, BUT THE FACTS ARE CLEAR. NIH'S OWN ESTIMATES CLAIM THAT BY THE YEAR 2000 \$50 BILLION IN REVENUES AND THOUSANDS OF NEW JOBS CAN BE ATTRIBUTED TO THE BIOTECHNOLOGY FIELD. WHILE I UNDERSTAND THE NEED TO ADDRESS POSSIBLE POLICY CONCERNS I HOPE THAT THE SUBCOMMITTEE WILL MOVE PRUDENTLY.

FINALLY, MR. CHAIRMAN, AS YOU KNOW, SANDOZ PHARMACEUTICAL CORPORATION WAS UNABLE TO TESTIFY THIS MORNING CONSEQUENTLY, SANDOZ HAS PROVIDED ME WITH A WRITTEN STATEMENT WHICH TOGETHER WITH THEIR MARCH 5TH LETTER, I HEREBY REQUEST TO BE INCLUDED IN THE HEARING RECORD.

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Opening Statement of the
Honorable James H. Bilbray

3/11/93

Mr. Chairman. As the Clinton Administration gears itself to tackle the necessity of health reform, I must again commend your desire to tackle one of the most obvious signs of the need for reform, the high price of prescription drugs. It is of particular interest that you and the Subcommittee have chosen today to hit upon one of the root causes of these high prices and the fact that taxpayers do not appear to be benefitting from the marketing of federally subsidized research.

I hope that in their testimony, both Dr Healy and the representative from Scripps will shed some light on why the current practices have been allowed to continue. Under these practices, federally subsidized laboratories such as Scripps have been allowed to enter into agreements with pharmaceutical companies, foreign and domestic, which give the companies exclusive rights to technologies and developments discovered at the laboratories. In return, the lab receives a lumpsum payment. Labs such as Scripps will argue that these agreements and payment provide a necessary avenue for more badly needed research money. However, it can be contended that the payment that a lab such as Scripps receives from a company such as Sandoz from Switzerland, \$300 million, is nothing more than payment for taxpayer funded research. In the 10 years of the Scripps/Sandoz agreement, the NIH will provide Scripps with approximately \$1 billion in funding.

However, this situations worsens , when you consider that upon receiving the rights to this research, not only those the NIH and the federal government loose all control over it, but the company that now owns it can proceed to market it and price it as they wish, without regard to the taxpayer. More than often, under the guise of R & D cost, which in cases such as this amount to no more than a payoff, these companies will charge exorbitant prices.

I look forward to Dr. Healy's thoughts on rectifying this problem and to the opinion consumer advocates such s Mr. Nader on this topic. I hope that as we prepare ourselves to tackle the problems of America's health care crisis, we will also undertake the opportunity to correct situations such as this one in which the taxpayers are loosing the opportunity to afford lifesaving and live improving drugs which they have clearly aid for.

HONORABLE JAY KIM
41st DISTRICT CALIFORNIA

OPENING STATEMENT
SMALL BUSINESS SUBCTTE. ON REGULATION/BUS. OPP.
MARCH 11, 1993

MR. CHAIRMAN, I LOOK FORWARD TO SERVING ON THIS
SUBCOMMITTEE.

HOWEVER, I AM DISAPPOINTED THAT OUR FIRST HEARING IS NOT
FOCUSED ON THE GENERAL ISSUE OF THE HEALTH OF SMALL BUSINESS.
AMERICA'S SMALL BUSINESSES ARE HURTING AND THEY NEED OUR
HELP.....NOW!

THIS IS THE SUBCOMMITTEE ON REGULATION, BUSINESS
OPPORTUNITIES AND TECHNOLOGY. I HAVE JUST COME FROM THE
PRIVATE SECTOR WHERE I'VE BEEN ALL MY LIFE RUNNING MY OWN
SMALL BUSINESS. I WAS CONSTANTLY FACED WITH MORE AND MORE
CONFUSING FEDERAL REGULATIONS THAT BECAME OBSTACLES TO
GROWTH AND NEW JOB CREATION. I WANTED TO DO SOMETHING
ABOUT THAT, SO I RAN FOR CONGRESS AND HERE I AM.

I'M LOOKING FORWARD TO FOCUSING THE IMPACT OF FEDERAL
REGULATIONS ON SMALL BUSINESS. I THINK THAT SHOULD BE THE
NUMBER ONE PRIORITY OF THIS SUBCOMMITTEE.

-2-

PRESIDENT CLINTON HAS PROPOSED A MAJOR ECONOMIC STIMULUS PACKAGE WITH SPECIFIC EMPHASIS ON HELPING SMALL BUSINESS. THIS PACKAGE IS ON THE FAST TRACK IN CONGRESS.

WE OUGHT TO BE HOLDING HEARINGS FOCUSING ON THE SMALL BUSINESS OPPORTUNITIES AND EXAMINING WHETHER OR NOT THERE ARE OTHER ACTIONS THAT COULD BE TAKEN TO IMPROVE BUSINESS AND ECONOMIC GROWTH.

I THINK THERE ARE, NAMELY REGULATORY REFORM. I THINK THIS SUBCOMMITTEE IS BEST SUITED TO PURSUE THIS AGENDA. I THINK WE SHOULD BE DOING THAT NOW.

NO OFFENSE TO ANYONE HERE, ESPECIALLY OUR DISTINGUISHED WITNESSES LIKE THE DIRECTOR THE N.I.H., BUT I DO NOT SEE THE ISSUE OF JOINT PRIVATE-FEDERAL PHARMACEUTICALS AS A SIGNIFICANT PROBLEM FACING AMERICA'S SMALL BUSINESS COMMUNITY AND WARRANTING THIS URGENT HEARING.

ARE THERE ANY SMALL BUSINESS WITNESSES IN THE THREE PANELS BEFORE US? IT DOESN'T APPEAR SO.

-3-

THERE ARE MANY NEW FRESHMEN IN CONGRESS AND ON THIS SUBCOMMITTEE. WE DIDN'T COME HERE TO SUPPORT BUSINESS AS USUAL--WE CAME HERE TO GET THE JOB DONE.

I BELIEVE THAT IN THIS SUBCOMMITTEE THAT SHOULD MEAN CONCENTRATION ON THE NUMBER ONE ISSUE OF REGULATIONS AND BUSINESS OPPORTUNITIES AS THEY AFFECT AVERAGE SMALL BUSINESSES, NOT SPECIAL INTERESTS.

WHILE I DON'T THINK THIS IS THE BEST WAY TO GET STARTED, I HOPE OUR NEXT HEARINGS WILL REFLECT THE TOP PRIORITIES OF THE AMERICAN SMALL BUSINESS COMMUNITY.

MR. CHAIRMAN, I LOOK FORWARD TO WORKING COOPERATIVELY WITH YOU AND THANK YOU FOR YIELDING.

OPENING REMARKS

HON. SAM JOHNSON

THANK YOU MR. CHAIRMAN.

I WANT TO THANK OUR GUESTS FROM THE NATIONAL INSTITUTES OF HEALTH (NIH) AND THE REST OF THE PANEL FOR THEIR PARTICIPATION IN TODAY'S HEARING.

I LOOK FORWARD TO OUR PANEL'S DISCUSSION OF THE COOPERATIVE RESEARCH AND DEVELOPMENT AGREEMENTS (CRADA) BETWEEN TAX-EXEMPT MEDICAL INSTITUTIONS AND PRIVATE PHARMACEUTICAL COMPANIES. I REALIZE THAT SINCE ENACTMENT OF THE BAYH -DOLE ACT OF 1980, MANY SUCH AGREEMENTS HAVE BEEN MADE. I AM CONCERNED, HOWEVER, THAT THE TWO PARTIES IN QUESTION, SCRIPPS AND SANDOZ, ARE NOT PRESENT TO ADD TO THE PANEL'S DISCUSSION.

BACK HOME, MANY OF MY CONSTITUENTS ARE UPSET ABOUT THE HIGH COSTS OF PHARMACEUTICALS, PRESCRIPTION DRUGS AND VARIOUS OTHER MEDICAL PRODUCTS. I HOPE THAT AS WE CONSIDER THE TECHNOLOGY TRANSFER AGREEMENTS BETWEEN SCRIPPS AND SANDOZ, WE DON'T LOSE SIGHT OF THE PEOPLE THAT OUR ACTIONS ULTIMATELY AFFECT, OUR CONSTITUENTS.

STATEMENT BY
BERNADINE HEALY, M.D.
DIRECTOR
NATIONAL INSTITUTES OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN SERVICES
HOUSE COMMITTEE ON SMALL BUSINESS
SUBCOMMITTEE ON REGULATION, BUSINESS OPPORTUNITIES AND ENERGY
THURSDAY, MARCH 11, 1993

Mr. Chairman and subcommittee members, I am here today to testify about research support agreements between academic research institutions funded by NIH and industry. Within that context, you have asked that we consider whether and how such an agreement between the Scripps Research Institute and Sandoz Corporation complies with the policy objectives articulated by Congress in the Bayh-Dole Act of 1980 (P.L. 96-517).

The mission of NIH is the pursuit of science to improve human health. NIH and the institutions it funds conduct research at the frontiers of knowledge--often in collaboration with industry. Through technology transfer, the fruits of NIH-funded research are brought to the public by translating fundamental medical research into commercial products that improve the general health.

NIH and its grantees have played a vital role in laying a foundation of scientific knowledge and discovery. We have worked with industry to translate these discoveries into lifesaving diagnostics and therapeutics. In turn, this partnership has fostered the development of a strong U.S. biotechnology sector. Projections indicate that revenues from biotechnology will exceed \$50 billion by the year 2000 and produce thousands of jobs. NIH's support of research has helped make the United States the world's leader in the pharmaceutical and medical device industries, which are among the most promising sectors of this Nation's economy.

Central to this success is the Bayh-Dole Act, which governs the transfer of technology from NIH-funded research institutions to industry. Through this Act, the Congress has: encouraged collaboration between commercial concerns and nonprofit organizations, such as universities; promoted the patenting and licensing of inventions developed with Government funding; and, given preference in such activities to small business firms and those who manufacture in the United States. In the interests of expediting technology transfer and minimizing the costs of administering policies in this area, the Bayh-Dole Act also removed the NIH -- and all funding agencies -- as middlemen in the process. Rather than reviewing up-front the technology transfer capabilities of NIH grantees and establishing institutional patent agreements that permitted institutions to retain rights to their inventions, under Bayh-Dole institutions are automatically granted first rights to inventions without prior agency approval. Under Bayh-Dole, NIH now has more limited authorities. The Act does allow agencies to intervene, after the fact, so to speak, under certain conditions, with so-called "march-in rights." These "march-in rights" may be exercised:

- (1) if a specific invention is not being developed effectively to the point of practical application;
- (2) to alleviate health or safety needs;

- (3) to meet requirements for public use specified by federal regulations; and,
- (4) if a product is not being substantially manufactured in the U.S., but will be sold in this country.

To my knowledge, no federal agency has ever exercised these "march-in rights."

The Bayh-Dole Act effectively governs the bulk of NIH research as it is converted to practical application by universities and nonprofit institutions. More than 70 percent of NIH's \$10 billion budget supports research and research training in such extramural institutions throughout the Nation. Our agency's competitive grant and contract system encompasses over 28,000 research grants and about 1,400 contracts involving some 1,700 universities, medical centers and research institutions.

The history of patent activity subsequent to the passage of the Bayh-Dole Act reflects its success. For example, in the 10 years prior to passage of the Bayh-Dole Act in 1980, there were 890 patent applications filed based on inventions developed with NIH support. During the subsequent 10 years, however, some 2,617 patent applications were filed, representing a nearly 300 percent increase. These statistics and related studies have shown that since the passage of the Act, patenting and licensing are being pursued more aggressively. Over the past 12 years, we have not only seen an explosion in the licensing of inventions based on NIH sponsored research, but also we have seen much of this research lead to the creation of small businesses. Most importantly, the development of many new, important drugs and devices by both large and small enterprises has been facilitated.

Since enactment of Bayh-Dole, the climate for biomedical research and technology transfer has changed. Increases in NIH's appropriations have not kept pace with the rapidly-expanding research opportunities, causing research institutions to look elsewhere for support. At the same time, funding from industry for research has increased at a faster rate than federal support. Science has become increasingly international, and partnerships between U.S. universities and foreign entities and also small U.S. biotechnology companies and large foreign companies have increased. As the time between discovery and the practical application of discoveries has contracted, academic and industrial partnership has been further stimulated. The increasing success and importance of the biotechnology industries has drawn attention to the international competitiveness of this industry and to the issue of foreign access to U.S. discoveries and inventions.

For these and other reasons, the return on the public investment in research and development is being scrutinized more closely. Are jobs, new products, royalties or lower prices the appropriate measures of that return? To this question, Bayh-Dole provides only limited guidance and flexibility to act. Notably,

Bayh-Dole requires an "exceptional circumstances" determination to be made when an agency finds that restriction or elimination of a grantee's right to retain title to any subject invention will better promote the policy and objectives of the Act.

Joint ventures between nonprofit research institutions and industry have proliferated, and become more complex. The just-released study by the Congressional Office of Technology Assessment (OTA) entitled "Pharmaceutical R&D: Costs, Risks and Rewards" has identified 25 large-scale, multi-year pharmaceutical R&D arrangements between industry and academia. Since 1981, three of these involved foreign academic institutions and U.S. companies; six involved U.S. universities and foreign companies. The majority of the arrangements, however, were between U.S. academic institutions and U.S. industry. According to the OTA, relatively little is known about these arrangements.

The Scripps-Sandoz agreement appears to be one of these large-scale arrangements, but, unlike others, is said to encompass virtually all the research output of the Scripps Institute. The funds provided by Sandoz underwrite part of scientists' salaries and their research efforts and give some degree of economic security to Scripps. In exchange, the agreement reportedly gives Sandoz the right of first refusal to any future inventions. These global first refusal rights may seem to conflict with some of the policy behind Bayh-Dole, such as the preference for collaboration with small business and the promotion of free competition and enterprise. However, the grant of these global rights may not conflict with the U.S. Department of Commerce regulations implementing Bayh-Dole [37 CFR § 401.1(a)] provides for:

"...the right of research organizations to accept supplemental funding from other sources for the purpose of expediting or more comprehensively accomplishing the research objectives of the government sponsored project."

Similarly, [37 CFR § 401.7] states that the small-business preference:

"...is not intended, for example, to prevent nonprofit organizations from providing larger firms with a right of first refusal or other options in inventions that relate to research being supported under long-term or other arrangements with larger companies."

Thus, the Scripps-Sandoz agreement illustrates a potential contradiction between what some view as the policy underlying the Bayh-Dole Act and regulation.

The Bayh-Dole Act articulates multiple policies and objectives which may prove difficult to reconcile. For example, an action by a nonprofit organization, while clearly advancing one objective of the Act, such as promoting collaborations between commercial and nonprofit organizations, might not advance--and may, in fact,

appear to undermine--another objective of the Act, like promoting free competition and enterprise. Needless to say, application of the objectives of the Bayh-Dole Act requires a balancing of statutory objectives in the overall best interests of the American public. That is the challenge for NIH and other agencies that support research. It would be foolhardy and irresponsible for Federal agencies to champion open competition at the expense of denying the institutions it supports an opportunity to seek additional research funding. To restrain collaborations between Federal grantees and industry simply because the competitive advantage of a given collaboration may not be readily apparent, while simultaneously undermining the best opportunities to rapidly commercialize inventions, would also be unwise. In short, we must achieve a balance, remembering that the general intent of the legislation is to promote product development--not commercial monitoring.

Under current Federal statutes and regulations, grantees and contractors are, except in limited circumstances, given broad discretion to elect title to and license inventions made under Federal grants and contracts. Within this broad authority, the Scripps-Sandoz case raises a number of policy questions. In order to address this matter in a judicious, thorough, and fair manner, NIH has done or will recommend the following:

- 1) We have asked Scripps for a copy of the research support contract which sets forth the specifics of its agreement with Sandoz and any other similar agreements with industry. We have asked more than 100 grantee institutions for copies of commercialization agreements relating to NIH funding in which institutions grant to industry exclusive rights or options to such rights. In particular, institutions have been asked to describe fully the financial arrangements with companies, what interest in research results or products the companies will receive, and how the agreements will affect the conduct of research and the dissemination of research results.
- 2) The Office of the NIH Legal Advisor will review these commercialization agreements in the context of the Bayh-Dole Act and other applicable statutes.
- 3) If our review raises issues with regard to our responsibilities under the Bayh-Dole Act or other applicable statutes, NIH will determine the appropriate steps to be taken on a case-by-case basis.
- 4) To deal with the broader policy issues, NIH has organized an internal "Task Force on the Commercialization of Intellectual Property Rights from NIH-Supported Extramural Research." This task force will identify issues presented by these agreements, seek public opinion, and make recommendations to the NIH Director.

As we proceed with these actions, we are ever mindful that the policy debate which relates to the Bayh-Dole Act and technology transfer touches all Federal agencies. We will work with others at HHS and perhaps other agencies to assess the complex and emerging national and international policy issues that we now face in large part because the Bayh-Dole has been so successful in fostering academic-industrial partnership--and also because Federal research dollars cannot fully exploit the available opportunities in biomedical research.

In conclusion, Mr. Chairman, as we find ways to address concerns raised by the evolution of cooperative research arrangements, this consideration must remain paramount: NIH must continue to seek the rapid development of discoveries into useful products in order to fulfill our mission to save and improve the lives of the American people. If the fruits of our research do not reach the public we serve, we have failed in our mission.

OTA TESTIMONY

Statement of

Judith L. Wagner, Ph.D.
Senior Associate, Health Program
Office of Technology Assessment

accompanied by

Michael E. Gluck, Ph.D.
Senior Analyst, Health Program
Office of Technology Assessment

Before the

House Committee on Small Business
Subcommittee on Business Opportunities, Regulation, and Energy

On

Relationships Between the Pharmaceutical Industry and
Academic and Nonprofit Research Institutions

March 11, 1993



Congress of the United States
Office of Technology Assessment
Washington, DC 20510-8025

Mr. Chairman, we are here today at your request to offer background testimony on the interactions between academic and non-profit research institutions and industries in the conduct of biomedical research. As you know, OTA recently completed a study of pharmaceutical R&D (11). Although OTA did not analyze the policy implications of the sizable Federal support for academic-based biomedical research, we did document the available data on the respective roles of the government and industry as funding sources. We are here today to provide you with a brief summary of that information.

Collaborative arrangements between academic researchers and pharmaceutical firms represent an implicit transfer of federally supported research and knowledge to the private sector. As opportunities to commercialize research findings in the life sciences have grown, so too has interest in commercial relationships designed to make use of these results in the marketplace (9).

The Historical Context for Collaboration Between Universities and the Pharmaceutical Industry

The pharmaceutical industry has a long tradition of cooperation with academia (7). When World War I eliminated the supply of pharmaceuticals from Germany, American drug companies realized the need to develop their own products. They established ties with universities in order to recruit scientific manpower and to capitalize on academic research with pharmaceutical potential.

Academics were receptive to such cooperation (7). During the postwar period, U.S. pharmaceutical firms established multifaceted strategies for cooperation with universities. They built ties with academic scientists by attending scientific meetings in force, visiting academic laboratories on a regular basis, sponsoring lectures by academic scientists at company facilities, sponsoring awards through academic societies, and developing lists of leading scientists within relevant fields to receive regular written updates on advances occurring within industrial laboratories. They also began to sponsor fellowships and trainees in universities. Between 1925 and 1930, for example, Squibb spent a seventh of its research budget on such fellowships (7).

Collaboration between academia and the pharmaceutical industry on basic research diminished steadily between 1940 and the 1970s as alternative sources of support for university research (mainly the government) increased and as the growth in industrial research laboratories reduced firms' reliance on academia (7). Yet, the amount of clinical research sponsored by the industry and conducted by academia grew significantly over this period, particularly after the 1962 amendments to the Food, Drug and Cosmetic Act (21 U.S.C. 301 et seq.) required drug sponsors to establish effectiveness as well as safety of new products.

Clinical research requires collaboration with academic medical centers that have the physician-researchers, the patients, and the infrastructure to test new drugs. Hence, even as university-industry relationships revolving around laboratory research diminished in the 1950s to 1970s, pharmaceutical firms maintained formal and informal clinical relationships with academia.

Beginning in the late 1970s, the number of collaborations with universities during the discovery phase of research began to expand once more. Most observers have tied this trend to the development of biotechnology techniques in university laboratories (5,7,9). Large pharmaceutical firms turned to academia to learn these techniques. In many instances, the principal founders of new biotechnology companies came from academia and attempted to keep their university affiliations. In the 1980s academic scientists and venture capitalists, recognizing the value of these advances in the life sciences, sought to commercialize university research through startup firms that also maintained close relationships with academic laboratories (5).

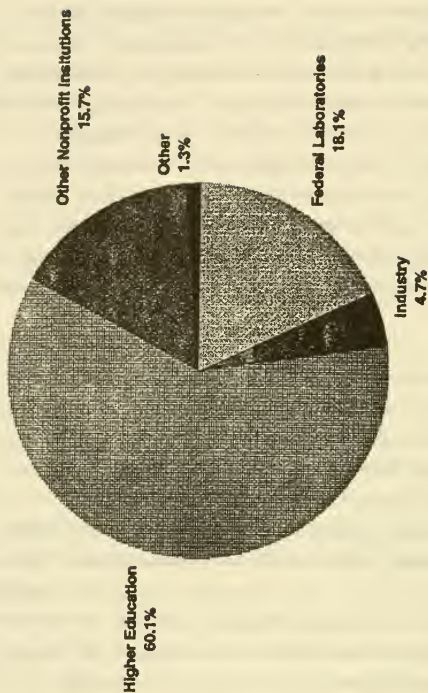
Recent Collaboration

Today's collaborations take place against a backdrop of pervasive government funding for biomedical research in academia. Of the \$7.7 billion in health R&D funded by the National Institutes of Health (NIH) in 1991, over three-quarters goes for research performed in higher education and other nonprofit research institutions (see figure 1).

Even within the individual academic research laboratory, financial support from industry piggybacks on the more extensive government support. As figure 2 indicates, in 1984 less than one-quarter of principal investigators in the life sciences who used biotechnological techniques¹ at 40 of the 50 most research-intensive universities received any support from industry (2). In addition, the vast majority of those faculty who received any research

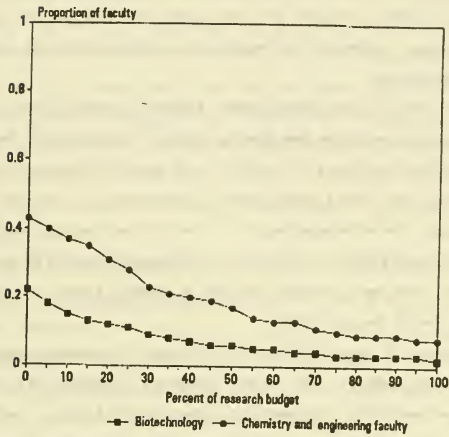
1. The data also indicate that the vast majority of life scientists responding to the survey (81 percent) used biotechnological techniques.

Figure 1--Where NIH Health R&D is Spent, 1991



SOURCE: U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, NIH Data Book 1992 NIH Pub No. 92-1261 (Bethesda, MD: National Institutes of Health, September 1992).

Figure 2-Proportion of Faculty Receiving a Given Percent or More of Research Budgets From Industry, 1984



SOURCE: Reprinted with permission from D.B. Blumenthal, M.E. Gluck, K.S. Louis, et al, "University-Industry Relationships in Biotechnology: Implications for the University," Science 232:1361-1366, 1986.

support from industry still got most of their research support from government and the nonprofit sector; only 10 percent of principal investigators received more than 25 percent of their research support from industry. In comparison, faculty members in chemistry and engineering received industrial funds almost twice as frequently.

These data may not reflect current industrial funding levels, because biotechnology research has been growing rapidly. Unfortunately, there is no centralized source of data to track the total amount of pharmaceutical and health-related R&D that industry funds in universities and nonprofit research institutions. Our understanding of the extent of such support comes from anecdotes, partial lists of large-scale arrangements compiled by various researchers, and some systematic research on industry support of biotechnology research done in the mid-1980s².

There are at least four kinds of collaboration between academia and the pharmaceutical industry. The two most common are project-specific research support and consulting arrangements with pharmaceutical firms. Two less common forms of collaboration-- (1) large-scale, multiyear investments in academic research centers by private companies, and (2) ownership or control of industrial firms by a university or its faculty--have received much more popular attention in recent years, perhaps because of their novelty in the life sciences and their potential impact on traditional academic values and norms of behavior (5).

2. The researchers at Harvard and the University of Minnesota who did this research in the mid-1980s are currently gathering data with which to make new estimates of the current extent of industrial funding of biotechnology and its consequences.

Although no overall estimate exists of industrial support for individual pharmaceutical or health-related research projects, one group of researchers did make estimates for the subset of that research involving biotechnology techniques. Their work indicates that in the mid-1980s, industry funding of these individual research projects in academia totaled between \$85 and \$135 million in 1984, or between 8 and 24 percent of all funds available for biotechnology research in academia (3).³ They also found that spending per project was less than the average size of NIH grants, and that these projects were typically of a shorter duration, suggesting that industrially supported research may be more focused and applied in nature than that funded by government (3,12).

Life science faculty at major research-intensive universities also receive support through consulting arrangements with private firms. According to the same researchers, about 40 percent of such faculty had consulted with industry for money at least once over the 3-year period ending in 1984 (2).

Large-scale collaborations between pharmaceutical companies and academia are largely a phenomenon of biology and pharmacology (13). Although these agreements may represent extensive support and collaborative opportunities for the faculty involved, they are relatively infrequent. However, because no good estimate exists of the total amount of industry support of pharmaceutical and health-related R&D, these arrangements could constitute the bulk of all industry money flowing into the university and nonprofit research sectors. A

3. Because biotechnology has applications beyond biology and medicine, some of this estimated industrial support of academic research went for work in fields such as agriculture.

list compiled by Webster and Etzkowitz of most such relationships with the pharmaceutical industry through 1990 is shown in Table 1. In some cases, the industrial partner may create an entire physical structure in which industrially-supported work takes place; in others the company may support research in an existing academic facility.

Among other potential benefits to the industrial partner, some collaborations allow the placement of company scientists in university laboratories. Table 1 also shows that the industrial commitment in these relationships is often for a longer period than is industrial project-specific support. Though some systematic research about the structure, workings, and scientific or commercial outcomes of these large collaborations is currently underway, little is known about them today (5,14).

Private industrial ventures begun by universities or their faculty have created controversy about the appropriate limits of commercial activities on campus. Such startup ventures come in two main varieties: 1) commercial ventures established directly by the university to commercialize academic research and to benefit the school financially; and 2) firms founded by individual faculty members to commercialize their own research, usually for the financial benefit of the founders and other stockholders.

One of the earliest universities to try to capture the commercial benefits of its faculty's research is the University of Wisconsin, whose Wisconsin Alumni Research Foundation (WARF) dates from the 1920s. All faculty at the University of Wisconsin are required to assign the rights to patents arising from their work to the independent WARF, which then attempts to license the technology. Proceeds are shared by the university and the inventing faculty member. The vast majority of all its income is attributable

Table 1—Large-Scale Agreements Pharmaceutical R&D Between Universities and Industry

University/firm	Funds (\$ millions)	Duration (years)	Year established	Area
Harvard University Medical School/Monsanto.....	23.5	12	1974	Cancer angiogenesis
Massachusetts General Hospital/Hoechst.....	4.2	12	1978	Genetics
Rockefeller University/ICI.....	70.0	12	1981	Molecular biology
Rockefeller Institute/Johnson & Johnson.....	30.0	Open-ended	1981	Synthetic vaccine
Washington University/Mallinckrodt.....	3.8	5	1981	Hybridomas
Harvard University Medical School/Dupont.....	6.0	5	1981	Genetics
Harvard University/Celanese.....	1.1	5	1981	Enzymes
Harvard University/Johnson & Johnson.....	1.0	Open-ended	1981	Biotechnology
Rockefeller University/Monsanto.....	4.0	5	1982	Photosynthesis
Washington University/Monsanto.....	100.0	12	1982	Biomedical research
Harvard University/Bristol Myers.....	3.0	5	1982	Anticancer drugs
Harvard University/Bristol Myers.....	7.5	5	1982	Molecular genetics
Harvard University/Kodak (Sterling).....	0.5	Open-ended	1983	DNA
Columbia University/Bristol Myers.....	2.3	6	1983	Gene structure
Harvard University/Monsanto.....	20.0	5	1983	Glycoproteins
Harvard University/Fidia.....	62.0	Open-ended	1985	Neurosciences
Harvard Medical School/Takeda.....	1.0 ^a	Open-ended	1986	Angiogenesis factors
Harvard University/Squibb.....	32.0	7	1987	Pharmacology (central nervous system)
Harvard University/SmithKline Beecham.....	2.2	5	1988	Respiratory disease
Harvard University/SmithKline French.....	4.0	5	1988	Molecular medicine
Harvard University/Beecham.....	8.0	10	1989	Neuropsychobiology
University of London/Squibb.....	47.0	7	1989	Molecular biology: proteins
Massachusetts General Hospital/Shiseido.....	85.0	1	1989	Dermatology
University College London/Eisai.....	75.0	15	1990	Neuroscience
Harvard University Medical School/Hoffman-La Roche.....	10.0	5	1990	Medicinal chemistry
Massachusetts General Hospital/Bristol Myers Squibb.....	37.0	5	1990	Cardiovascular
University of California at San Diego/Ciba Geigy.....	20.0	6	1990	Rheumatoid and osteoarthritis

^aHarvard Medical School/Takeda contract is \$1 million per annum (open-ended).

SOURCE: A.J. Webster and H. Erzkowitz, Academic-Industry Relations: The Second Academic Revolution: A Framework Paper for the Proposed Workshop on Academic-Industry Relations (London, England, Science Policy Support Group, 1991).

to a single early patent of importance to the dairy industry, which suggests that such enterprises may be unable to generate much patent income for the university (1).

Despite the mixed success of the WARF example, during the 1980s a number of other research-intensive universities created similar institutions to commercialize campus research (5). An important feature of almost all these enterprises is that they are organizationally independent of the universities that own them. The separation is intended to prevent commercial considerations from perverting the traditional academic values of the university.

Critics of these arrangements have questioned whether true organizational separation is possible given the frequent involvement of individuals with strong ties to the parent university in the decisions of the commercial enterprise (1,5). Indeed, Harvard University soundly rejected a 1980 proposal to establish a firm to commercialize research because it was considered incompatible with the university's central missions of learning and the pursuit of knowledge (4). By 1988, the attitude had changed; the university reversed itself by establishing Medical Science Partners (MSP), an enterprise designed to commercialize biomedical research findings in a manner similar to WARF. In doing so, the university faced little of the faculty criticism or media attention that accompanied the 1980 proposal (15). To date, no evidence is available on whether these enterprises have in fact stimulated commercialization of research findings or whether the earlier fears of the critics were justified.

In the 1980s, many faculty in the life sciences founded companies with products or services based on their own research (9,10). Some early products based on biotechnology (such as diagnostic tests using monoclonal antibody

technology) had a relatively fast R&D period, thus generating early revenues and increasing interest in such enterprises among other faculty and the investment community (8).

Faculty-founded companies led universities to question how deeply involved in the commercial enterprise a faculty member should become while maintaining his or her university affiliations (5,7,13). In recent years, some universities have banned faculty equity holding in firms that support the faculty members' own research, while others have relied on faculty disclosure of such financial interests and a case-by-case consideration of their appropriateness (3,6).

Although individual cases have been controversial, the scanty evidence that exists suggests the phenomenon of faculty equity-holding in commercial enterprises is actually very infrequent. In 1985 only 8 percent of faculty involved in biotechnology at universities reported holding equity in a firm whose products or services were based on their research (2). In addition, only 0.5 percent held equity in firms from whom they also received support for their university research. Although responding faculty may have underreported these activities, the 8 percent no doubt includes equity ownership in nonstartup firms.

The Federal Role in University-Industry Relationships

The current prevalence of these arrangements is partly due to the scientific opportunities to commercialize academic research created by biotechnology (9,10) and, perhaps more importantly, to the 1980 enactment of the Bayh-Dole Patent and Trademark Act of 1980 (Public Law 96-517). This law gave universities, nonprofit organizations, and small businesses the rights to

inventions resulting from research supported with Federal grants. It also required these institutions to share any royalty income from patents with the individuals responsible for the invention.⁴ Thus, under this current law, the Federal government essentially lacks any legal authority to control how universities and nonprofit research institutions decide to award rights to research results produced on their campuses.

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STATEMENT OF RALPH NADER

before the
Subcommittee on Regulation, Business
Opportunities, and Energy

of the
Committee on Small Business
United States House of Representatives

on

PRIVATE SECTOR AGREEMENTS TO MARKET
FEDERALLY FUNDED RESEARCH

March 11, 1993

P.O. Box 19367, Washington, DC 20036 / (202) 387-8030

Introduction

Mr. Chairman and members of the Subcommittee, I am pleased to appear today to discuss the consequences of more than a decade of Congressional and Executive Branch efforts to alienate taxpayers from ownership or control of publicly funded research and development. As you know, this is a topic that has long been neglected by the Congress especially during the Reagan giveaway years. More recently, it has been the subject of numerous investigations by our Taxpayer Assets Project focusing on the management of federal information resources and federally funded pharmaceutical inventions. Today this subcommittee is focusing on arrangements which illustrate the arrogance of those who control billions of dollars in commercially valuable research and development paid for by taxpayers.

The Bayh-Dole Act, passed in 1980, was a watershed disaster which signaled a rapid decline in public accountability over the management of vast resources created with public funds. (See Appendix for further information on the Bayh-Dole Act and other laws relating to the commercialization of federally funded medical technology.)

This Act, which gave certain profit and non-profit organizations title to patents and other intellectual property rights on federally funded research, was followed by dozens of Congressional and Presidential actions which have further eroded the public's ownership or control over important technology and information resources and increased the private monopoly power of companies who sell these resources back to the citizens who paid for them in the first place. The 1985 amendments which eliminated the "needs" test for federal Orphan Drug Act exclusive marketing privileges on drugs, the increasing emphasis on the exclusive licensing of federal research, the widely expanding use of Cooperative Research and

Development Agreements (CRADAs) to allocate exclusive property rights to federal research before discoveries are in hand, the changes in the Federal Acquisition Regulations (FAR) which give corporations exclusive commercial rights to vast federal information resources developed entirely with federal funds, and the increasing secrecy relating to public records which contain information about corporate activities are among the many actions which have reduced the power of the American people to demand accountability from the public officials who spend our money and the organizations which acquire windfalls from these public expenditures.

The key features of these actions are that they transfer ownership of public property to private interests free of charge or at bargain basement prices, they produce or increase monopoly power and they shelter these actions from public review through secrecy.

The Scripps Agreements

In 1980 Congress passed the Bayh-Dole Act, giving non-profit institutions and small businesses broad intellectual property rights, including patents, from taxpayer-supported research and development. The Scripps Research Institution (Scripps), located in La Jolla, California, has subsequently entered into a number of partnerships with large drug companies and small biotechnology firms. We are studying three of these agreements, and each case highlights important public policy concerns.

The Johnson and Johnson Agreements

Beginning in 1981, Scripps entered into a series of agreements with Johnson and

Johnson (J&J), giving this firm the first right of refusal to obtain exclusive marketing of Scripps's research, including hundreds of millions of dollars of research funded by the National Institutes of Health (NIH). J&J paid a reported \$100 million for this privilege, which, according to J&J officials, will extend through 1996.¹

While in many respects the Scripps/J&J agreement is not unlike many corporate/university agreements that exist today to commercialize federally funded research products, it bears discussion. First, while we are unable to obtain copies of any of the Scripps/J&J agreements, it is quite likely that, like most similar arrangements, there are no restrictions on the pricing of new government-funded pharmaceutical inventions, other than what the market will bear. Of course, under the Bayh-Dole Act, these institutions do not have a legal obligation to ensure that the public investment is protected.

As described by historian David Noble in an 1984 article in the National Education Association (NEA) *Journal Thought and Action*, private corporations use such agreements to "gain privileged access to and considerable leverage over finite public resources . . . socializing the risks and costs (but not the benefits) of private enterprise."² Noble's use of the word "leverage" is particularly apt in the case of the Scripps/J&J agreements, since the private pharmaceutical company's \$100 million payment over 15 years gives the company exclusive rights to commercialize the fruits of as much as \$100 million per year in Scripps research funded by the federal government. In a March 1982 talk at the Massachusetts

¹Among the products that J&J obtained from Scripps are Leustatin (2CDA), a treatment for Hairy Cell Leukemia, and factor 8, a clotting agent for hemophiliacs.

²David Noble, "Science for Sale," *Thought and Action: The NEA Higher Education Journal*, 1, 1984, pages 25-39.

Institute of Technology (MIT), Albert Gore, Jr., then a member of the House of Representatives, discussed how such agreements allow corporations to benefit from years of taxpayer supported research and "skim the cream off the top," blurring the distinctions between "propriety and proprietary interests."³

One result is that corporations obtain monopoly rights to technologies that were invented through public expenditures, forcing consumers to "pay twice," once for the development of technology as taxpayers and a second time as consumers.⁴ I should add that when paying the "second" time, consumers face prices charged by monopolies.

A further issue involves the burgeoning problem of conflicts of interest between the managers of federal research and the corporations who seek monopoly control of that technology.

In the case of the J&J agreements, the conflict of interest issue concerns a reported personal consulting agreement between Dr. Richard Lerner, the president of Scripps, and J&J, the firm that owns the first right of refusal to Scripps research. This agreement was disclosed by Craig Rose, a reporter for the *San Diego Union-Tribune*, in an article published on March

³As reported by Noble.

⁴The paying twice issue has been raised often in regard to such agreements. In a March 4, 1983 letter to *Science* referring to a contract between Hoffmann-LaRoche Corporation and the University of California over the development of interferon, Rockefeller University biologist Philip Siekevitz raised this issue, and said:

The initial research was paid for by taxpayers, through the National Institutes of Health . . . The question then is, Who gets the financial reward if the protein proves to be of commercial value? As it now stands resolved both the University of California and Hoffmann-LaRoche will get something; but what about the taxpayers?

5, 1993, which describes the work of this subcommittee's investigations, including a specific request for personal contracts between key Scripps officials and companies such as J&J and Sandoz which have contracts with the Scripps Institute.⁵ As reported by Rose, Scripps Senior Vice President William Beers said:

Richard [Lerner] has a consulting contract with J&J . . . He consults for them and can be asked for advice on particular problems they are having. He might consult for J&J on technology that Scripps has licensed to the company.

Beers is also quoted as saying that Scripps is aware of other consulting agreements with Scripps researchers, and that these agreements are "nothing unique" to Scripps. The Subcommittee's work in bringing these and similar agreements to light is commendable and necessary. Why does J&J need to have a personal consulting agreement with Dr. Lerner, the president of Scripps, when it already owns the rights to Scripps research? What is Dr. Lerner really compensated for? As you know, when Scripps discovers a pharmaceutical invention, Scripps then enters into negotiations with J&J over issues such as Scripps' royalties and profit sharing. By working for two masters, Scripps and J&J, Lerner is in a position to personally profit at the expense of the non-profit research institution which he runs. If these agreements are, as claimed by William Beers, "nothing unique," there are widespread conflicts of interest in the licensing of federally funded research, a situation which demands aggressive and thorough investigation by the Congress and the Clinton/Gore Administration.

Moreover, the existence of the consulting contract between Dr. Lerner and J&J was was not disclosed by J&J, raising questions about the strategy of the firm and the propriety of

⁵Craig D. Rose, "Scripps' dealings probe widened," *The San Diego Union-Tribune*, March 5, 1993.

the agreement. On March 5, 1993, the same day that the consulting agreement was reported in the *San Diego Union-Tribune*, and days after your Subcommittee had made inquiries about such agreements, Michael Ward of the Taxpayer Assets Project asked J&J spokesman Robert Kniffen the following questions, and received the following answers:

- Q1. Does or did J&J have any contracts with staff or board members of the Scripps Institute?
- A1. Not to my knowledge, no.
- Q2. Could I have a more definitive answer, could you check this for me?
- A2. We would not consider that anybody's business. Agreements we have with individuals are a private matter.

In our experience, this arrogance is, to use William Beers' expression, "nothing unique" within the industry.

The Cytel Joint Venture

The disclosure that Dr. Lerner has a personal consulting contract with J&J was not the first time that conflicts of interest within Scripps have been reported. In an earlier news story, Craig Rose reported that Dr. Lerner was a shareholder and board member of Cytel Corporation, a joint venture between Scripps and Sequel Therapeutics, a small biotechnology firm in the San Diego area, to develop vaccines. The fact that Dr. Lerner has claimed to have recused himself from the negotiations on the Cytel joint venture hardly allays concerns about that agreement, since as president of Scripps, Dr. Lerner will influence the promotions and future employment of the Scripps employees who do negotiate.

The Sandoz Agreement

The recently announced Scripps/Sandoz agreement involves payments of \$300 million to Scripps in return for a ten-year first right of refusal on the new technologies developed at Scripps. This agreement, which will begin in 1997, will likely involve more than \$1 billion in NIH-funded research. Based upon what little we now know, we can conclude there is little about the Scripps/Sandoz agreement that is unusual, except that the amounts of money are larger and that the agreement has generated considerable publicity.

Much of the publicity has focused on the fact that Sandoz is a foreign-owned firm, and that as a consequence of the agreement, it will be subsidized by U.S. taxpayers. Whether or not the Sandoz agreement is plagued with the conflicts of interest seen in the J&J or Cytel agreements remains to be seen.

The high visibility of the Sandoz deal is an embarrassment for the biotechnology and pharmaceutical industry, since the principle rationale for today's generous federal "technology transfer" laws is that they benefit U.S. companies. However, it is important to note that nothing in the current federal statutes prohibits such agreements, and in fact, university partnerships with foreign-owned firms are common. In the current issue of *Atlantic*, author Elliott Negin notes that a recent GAO study of 35 major research universities found that 24 had at least one industrial liaison with a foreign interest, while in total 499 foreign corporations were involved.⁶ MIT, Stanford and the University of California at Berkeley accounted for 58 percent of the surveyed agreements with foreign corporations.

It is important to note that many U.S. corporations participate in research programs

⁶Elliott Negin, "Education: Why College Tuitions Are So High," *Atlantic*, March 1993.

with foreign universities. For example, Bristol-Myers Squibb recently entered into agreements with Oxford University (1987, seven years, \$32 million) and the University of London (1989, seven years, \$47 million).⁷ Congress should gather information about the ways that these foreign research institutions manage contracts with U.S. pharmaceutical firms. However, it is also important to note that most European countries have the authority to control pharmaceutical prices, a critical authority that is lacking in this country.

Public Accountability

The Clinton/Gore Administration has announced large increases in federal funding for new "partnership" agreements with industry in a wide range of areas. The problems that the Subcommittee are investigating in the area of pharmaceutical research funded by NIH are only one element of a larger picture. None of the problems that will be discussed today are unique to the pharmaceutical industry. Conflicts of interest, anticompetitive practices and deep taxpayer subsidies abound in federal research efforts targeted at agriculture, energy, information technologies and many other areas. The lessons learned today should not be forgotten in the rush to finance these new federal research projects.

The massive corporate investments in lobbying, campaign finance and public relations constitute an enormous threat to the public interest, but in many cases they are augmented by

⁷As reported in A.J. Webster and H. Etzkowitz, *Academic-Industry Relations: the Second Academic Revolution: A Framework Paper for a Proposed Workshop on Academic-Industry Relations* (London, England, Science Policy Support Group, 1991). Also reported in the U.S. Congress, Office of Technology Assessment, *Pharmaceutical R&D: Costs, Risks and Rewards*, OTA-H-522 (Washington, DC: U.S. Government Printing Office, February, 1993), page 208.

lobbying efforts by elite educational and research institutions, that not only seek to enrich endowments and salaries, but also to create opportunities for windfall personal enrichments, as university presidents and trustees, senior faculty and researchers and others become publicly subsidized venture capitalists, cashing in on stock deals and consulting agreements. It is worth noting that among the most effective proponents of the Bayh-Dole Act was the American Council on Education, and that the current models for privatizing federal research owe much to the visions of Vannevar Bush, the head of the federal Office of Scientific Research and Development (OSRD) during World War II, who was a former Dean of M.I.T. as well as a director of AT&T, Merck and Raytheon.

The flaws of current federal policies were plainly stated in a 1980 minority report on the Bayh-Dole Act. Congressman Jack Brooks said:

The major problem I have with H.R. 6933 is that it violates a basic provision of the unwritten contract between the citizens of this country and their government; namely, that what the government acquires through the expenditure of its citizen's taxes, the government owns. Assigning automatic patent rights and exclusive licenses to companies or organizations for inventions developed at government expense is a pure giveaway of rights that properly belong to the people.

... The Federal government has the equivalent of a fiduciary responsibility to the taxpayers of the country. Property acquired with public funds should belong to the public. Deviations from that fundamental principle should be allowed only where a compelling justification can be shown and where the voice of the public can be heard in protest.

These words are good advice for Congress today. The task is to create a statutory framework that guarantees that institutions managing federal research and development funds justify the terms of the transfer of public property rights upon a "compelling justification [that] can be shown," in an environment "where the voice of the public can be heard in protest." In order

to do this in a meaningful way, Congress must end the automatic give away of the taxpayers intellectual property rights, and it must pierce the secrecy which surrounds these agreements.

We are skeptical that many federal agencies, including the National Institutes of Health (NIH), are up to the task. The recent fiasco concerning the NIH efforts to develop a "fair pricing" mechanism of federally patent license and CRADA agreements is a case in point. Not only did the National Cancer Institute (NCI), a branch of NIH, fail to require Bristol-Myers Squibb to disclose any financial information which were relevant to the "fairness" of the pricing of ddI and Taxol, two government developed drugs, but it also withheld vast amounts of information from the public.

For example, when the Taxpayer Assets Project submitted a Freedom of Information Act Request to the National Cancer Institute (NCI) for the Bristol-Myers Squibb CRADA, the request was delayed until months after the July 1991 hearing held by this Subcommittee. The CRADA that was disclosed was heavily censored to the point of absurdity. For example, NCI withheld the section which stated that Taxol was being tested for the treatment of ovarian cancer, which had already been the subject of hundreds of newspaper and television stories, not to mention Bristol-Myers Squibb press briefings. NCI also withheld the actual language of the fair pricing clause, and told the Taxpayer Assets Project that the language was based upon its Model CRADA agreement. In fact, the BMS/Taxol CRADA contained a decidedly abbreviated fair pricing clause that omitted any right of NCI to request documentation of the fairness of the Taxol price, an omission later used by NCI to justify its

ignorance of the profits from Taxol.⁶

NCI officials have also shielded Dr. Robert Wittes from answering questions about his relationship with Bristol-Myers Squibb in the development of the Taxol CRADA. As an official of NCI, Dr. Wittes was responsible for reviewing a 1983 NCI agreement with Bristol-Myers, concerning the marketing of cisplatin, a highly profitable cancer drug developed at Michigan State University with federal funds before the passage of the Bayh Dole Act. Michigan State University obtained federal permission to grant Bristol-Myers a five year exclusive license to market cisplatin in 1977. By 1983 five firms asked the federal government for permission to market cisplatin under non-exclusive licenses. These firms argued that competition would benefit consumers, and also that they would be willing to finance new cancer research under terms determined by NCI.

NCI refused to allow non-exclusive licensing of cisplatin, and instead gave Michigan State University the right to grant Bristol-Myers an extension of its exclusive license. In return, Bristol-Myers Squibb agreed to lower the price of cisplatin by 30 percent, and to fund a reported \$35 million in cancer research.

Dr. Wittes was responsible for reviewing the Bristol-Myers research program. He was also widely believed to have had knowledge of NCI's taxol research. Dr. Wittes later left NCI to join Bristol-Myers, months before NCI announced it would allow firms 45 days to "compete" for the Taxol CRADA. Despite the compressed 45-day bidding period, Bristol-

⁶See James P. Love, Director, Taxpayer Assets Project, "Private Sector Pricing of Taxol and Other Pharmaceutical Inventions Developed with Federal Funding," Statement submitted to U.S. House of Representatives, Committee on Small Business, Subcommittee on Regulation, Business Opportunities, and Energy, January 25, 1993.

Myers Squibb was able to present a detailed development plan for Taxol, which included, among other things, the use of Hauser Chemical, NCI's own contractor, to manufacture Taxol. In an unusual version of the revolving door, Dr. Wittes later left Bristol-Myers following a merger with Squibb, and returned to NCI, taking with him whatever compensation package he had negotiated for himself.

The Taxpayer Assets Project was unable to talk with Dr. Wittes about his role in the preparation of the Taxol CRADA, or his compensation from Bristol-Myers. Moreover, NCI officials would not even provide the Taxpayer Assets Project with a copy of Dr. Wittes resume. A written request to Dr. Wittes from Dan Newman, who was writing an article for the *Multinational Monitor*, was ignored.⁹

While it is important to investigate the serious problems in the university and non-profit sector, it is also essential to make the federal government more accountable.

It will take much work to restore public confidence in the federal government's policies toward the management of federally funded research and development resources. The following suggestions will provide a start.

Recommendations

1. The Patent and Trademark Office (PTO) should require that all patent applications include a summary of federally funded research which contributed to the discovery. This information should be included in the PTO's Automated Patent System, a government funded online database of patent information. Citizens should be allowed

⁹Daniel Newman, "The Great Taxol Giveaway," *Multinational Monitor*, May 1992.

to search this information from their homes and offices, at fees that do not exceed the "incremental cost" of disseminating the information. In 1991 the Taxpayer Assets Project submitted this suggestion to the Subcommittee on Intellectual Property and Judicial Administration, but it has yet to be acted on.

2. All federal grant and contract recipients should provide uniform public reports to the federal government which disclose the terms of licensing agreements on research that was funded by the federal government and the income that is received from such agreements.
3. All federal grant and contract recipients should be required to disclose to the federal government and the public any potential conflicts of interest between the institution and the entities which receive the marketing rights to intellectual property developed with federal funds.
4. Congress should require all grant and contract recipients to provide non-exclusive licensing of technologies developed with federal funds, unless permission is received from the federal government to use exclusive agreements. That permission should be subject to a finding that the exclusive agreement is in the public interest under a procedure inviting public comments in public dockets. Exclusive agreements should be available for public inspection and comment.
5. The federal government should have the right to limit pricing on pharmaceutical drugs and other medical inventions. In determining "fair" prices, the federal government should take into consideration the subsidy role of government funded research.
6. Information about the licensing of publicly funded research and development resources

should be widely disseminated to interested consumer, taxpayer and citizen groups, using such modern information technologies as the Internet and the National Research and Education Network (NREN). This is needed because many interested researchers and citizens do not read the federal register on a daily basis. The use of electronic dissemination of public notices on exclusive licenses and other matters will greatly facilitate the dissemination of this information to citizens.

Appendix

Notes on federal policies to transfer ownership of federally funded R&D¹

Policies concerning the allocation of intellectual property rights from federally funded research have changed markedly since the second world war. There once was a broad consensus that federally funded research should be liberally shared with the public, either by allowing research to enter the public domain, or by licensing property rights such as patents on a non-exclusive basis. In recent years this has given way to a more proprietary approach.

Many of the important changes in federal policy occurred in the 1980s. These include the enactment of the Stevenson-Wylder Technology Innovation Act and the Bayh-Dole University and Small Business Patent Procedures Act, both passed in 1980, the amendments to the Bayh-Dole Act passed in 1984, and the Federal Technology Transfer Act of 1986.² President Reagan also issued a number of Federal Executive Orders and memorandums which broadened the rights of government contractors and grant recipients to obtain titles to federally funded research products and grant exclusive licenses for commercial development.³

¹Prepared by the Taxpayer Assets Project.

²The Stevenson-Wylder Technology Innovation Act (PL 96-480), Oct 25, 1980, encouraged the transfer of intellectual property rights from federal research to the private sector. It also provided for cooperative research agreements and for supporting Centers for Industrial Technology affiliated with non-profit institutions, which could take title to inventions developed with federal funds.

The Bayh-Dole Act University and Small Business Patent Act (PL 96-517), Dec 12, 1980, gave small businesses and non-profit institutions title to inventions that they developed under federal grants or contracts. The Act retained a license for government use.

A 1984 law (P.L. 98-620) repealed the 5-year limitation on the use of exclusive licenses by non-profit institutions that held title to inventions that had been developed with federal funds, and allowed non-profit organizations to take title to inventions when operating government owned laboratory facilities.

The Federal Technology Transfer Act (PL-99-502), Oct 20, 1986, expanded the ability of agencies and laboratories to enter into Cooperative Research and Development Agreements (CRADAs). CRADAs typically involve joint research efforts between the government and industry, where a private firm obtains a promise that it will obtain exclusive commercial rights to research data and patents that are produced by the parties.

³On February 18, 1983, President Reagan issued a memorandum instructing federal agencies, where not prohibited by law, to grant all contractors the same right to invention titles that the Bayh-Dole Act granted to small businesses and non-profit institutions. On April 10, 1987, President Reagan issued Executive Order 12591, instructing agencies to allow laboratories to enter into CRADAs and to develop a policy allowing contractors to retain rights to software and other technical data, with a reservation of royalty-free use to the

These measures accomplished the following:

- i. In those cases where federal research funds were managed by non-government personnel, contractors or grant recipients were given title to a wide variety of government funded research rights, with few restrictions on how these rights could be exploited.
- ii. In those cases where the federal government retained title to the research products (such as research carried out by government employees or by contractors or grant recipients who were not qualified to take title to the research) federal agencies were told to place an increasing emphasis on exclusive marketing agreements with firms to commercialize the research products.

Patent, copyright, trade secret status and other measures are used to control access and ownership of government funded research. Private corporations routinely obtain exclusive marketing privileges on everything from government funded software and technical databases to inventions of new drugs.

The rationales for this more proprietary approach to federal research are varied, but two stand out, in terms of the frequency to which they are employed and the degree to which they are believed:

- i. the need to provide incentives for the commercial development of a product, and
- ii. the need to prevent foreign interests from benefiting from U.S. funded research and development.

While these rationales are contradictory (the need to prevent foreign companies from developing US technology suggests that sufficient incentives already exist for commercial development), they are often used simultaneously as a catch-all to justify policies.

These policy guidelines, which apply to all areas of federally funded research, have received wide bipartisan support in Congress, due in no small part to aggressive lobbying and generous political contributions by companies in defense, energy, pharmaceutical, and other fields, which have benefitted from these transfers. Critics worry that universities are becoming too concerned with potential commercial rewards from research, and are abandoning important types of basic research or restricting the free flow of information among scientists. There are also concerns that the large emphasis on exclusive marketing agreements will harm

government. The order also reaffirmed the policy in his 1983 memo of waiving government title rights to contractors wherever possible. On December 22, 1987, President Reagan issued Executive Order 13532, requiring all agencies to remove licensing restrictions on inventions made with federal assistance.

consumers, or lead to anticompetitive practices, such as blocking the development of related technologies which would use the government research product as an input for a different product. Others have questioned the policies on the grounds that taxpayers should receive greater benefits from its investments.

Nowhere are these issues as important as in the medical field, where the public investment is enormous, and the product will not be a better microwave oven, but better health or even life itself. On the one hand it is important that there are proper incentives to develop new medicines and other health care technologies. On the other hand, consumers of medical technologies are uniquely vulnerable to monopoly pricing.

The Federal Orphan Drug Act is also an important mechanism for allowing private firms to obtain monopolies on government funded inventions. Since we have previously addressed this issue at length to other Committees of Congress, we will reference our earlier statements, and add only a few comments.⁴ Today the Orphan Drug Act is primarily viewed as a mechanism to obtain seven years exclusive marketing rights (a feature that was considered unimportant when the legislation passed a decade ago). Thus, the Act is most important when company's do not hold patents for the drugs. A common reason that a drug cannot be patented is because researchers have already reported results in academic journals. This is more likely the result of research funded by the government than research funded by the industry, since the drug companies are known for exercising tight controls on a researcher's right to publish before applications for patents have been processed.

Because much government funded research ends up in the public domain (although less now than before), the Orphan Drug Act has become an important mechanism to obtain patent like protection on substances that cannot be patented, because of government funded research which has been published in academic journals.

Limits on Administrative reforms

There are many things that the federal government can do administratively to correct the woeful inadequacies of agency policies on the pricing of government funded pharmaceutical inventions. The federal government can develop better approaches to negotiating or setting prices on government funded medical inventions, it can collect better information on the economics of drug development and profits, and it can place more emphasis on competition by requiring agencies to make findings that exclusive agreements are necessary, or by restructuring the negotiations for exclusive contracts so that companies negotiate on prices *before* partners are chosen for exclusive arrangements (getting more mileage from the *ex ante*

⁴See James P. Love, "The Orphan Drug Act and Government Sponsored Monopolies for Marketing Pharmaceutical Drugs," comments submitted to the Senate Judiciary Committee's Subcommittee on Antitrust, Monopolies and Business Rights, January 21, 1992.

competition that exists in these awards).

But there are also many problems that cannot be solved without addressing the reforms in the Bayh-Dole University and Small Business Patent Procedures Act or the Orphan Drug Act -- two deeply flawed laws that have very powerful constituencies. So long as the federal government grants titles to federally funded research conducted by universities and other contract and grant recipients, the Congress will not be able to control prices for many government funded drugs. For example, the 1990 NIH health care R&D budget included \$4.18 billion in work performed by universities and another \$1.8 billion was performed by other non-profit institutions.⁵ Until the Bayh-Dole Act is changed the federal government will be severely restricted in its ability to control prices for many important drug inventions that taxpayers have financed.

⁵This included about \$2.5 billion in funding of basic research at universities and colleges, which was nearly half of all federal funds for basic research given to colleges and universities. U.S. Department of Health and Human Services, *NIH Data Book, 1991*, NIH Publication No. 91-1261, (Dedicated, MD. NIH, September 1991).

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on Regulation, Business
Opportunities, and Technology, Committee on Small Business,
House of Representatives

For Release on Delivery
Expected at
9:30 p.m. EST
Thursday
March 11, 1993

FEDERALLY FUNDED RESEARCH

Controlling Inappropriate Access to Research Results

Statement by Jim Wells, Associate Director, Energy and
Science Issues, Resources, Community, and Economic
Development Division



Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the findings of our May 1992 report, University Research: Controlling Inappropriate Access to Federally Funded Research Results (GAO/RCED-92-104), and the implications it has for the issues being addressed by this hearing. Our report--which dealt with research grants awarded by the National Institutes of Health (NIH) and the National Science Foundation (NSF)--examined the growing interactions between universities and private industry and discussed the increased potential for conflicts of interest or other relationships that might give a particular company inappropriate access to, and therefore an unfair advantage in commercializing, the results of federally funded research.

This same kind of concern over conflicts of interest and other special relationships would apply equally to major, multimillion-dollar funding agreements entered into by nonprofit research institutions that receive substantial funding from the government, such as the Scripps Research Institute. This hearing is looking into business relationships between recipients of federal research grants and companies intent on commercializing the discoveries and, in particular, a new 10-year, \$300 million agreement between Scripps (a nonprofit biomedical research institute) and Sandoz Pharmaceuticals Corporation (a private drug firm). While we have not seen this agreement, we understand that NIH learned of it only after it was completed and announced by Sandoz in December 1992.

In summary, we believe that, as a general principle, the public interest is better served if the government--and, in this case, NIH--ensures that appropriate controls and safeguards are in place governing who gets access to and ultimately benefits from the results of federally funded research. In this regard, our May 1992 report recommended that NIH and NSF require that their grantees

have procedures in place to effectively manage potential conflicts of interest, such as by requiring that investigators and other key personnel disclose any outside interests as part of the grant award process. Similarly, we believe it is important that the government at least be consulted about any major, multimillion-dollar agreement that a university, hospital, or other nonprofit research institution seeks to negotiate with a private company if the institution receives substantial federal funding and rights to commercialize resulting technologies.

PERSPECTIVE

Let me provide some perspective on these issues based on our May 1992 report.

The relationship of federally funded research to technological innovation was transformed dramatically during the 1980s as new linkages were established among the academic community, industry, and the federal government. One of the primary changes strengthening links between universities, hospitals, and other nonprofit institutions (hereafter referred to as nonprofit organizations) and private industry was enactment of the Patent and Trademark Amendments of 1980 (P.L. 96-517). The act encourages nonprofit organizations and small businesses to commercialize inventions they make in whole or in part with federal funding by allowing them, with few exceptions, to elect to retain rights to such inventions. Nonprofit organizations then can transfer their rights to businesses by granting exclusive (sole) or nonexclusive (generally available) licenses.

Appropriate access to federally funded research can include (1) granting an exclusive license to commercialize resulting technology to a business that co-sponsored a research project, (2) granting an exclusive license to a business that did not fund the research but is considered best able to commercialize the

technology, or (3) encouraging the scientist who developed a technology to further develop and commercialize it by working with the licensee. In contrast, inappropriate access can occur if a business that has not sponsored a research project obtains inside information about it or gets favored treatment in obtaining license rights to the resulting technology. Such inappropriate access could result from a financial or personal relationship between the business and a member of the nonprofit organization, or a financial relationship between the business and the nonprofit organization itself--such as through a major, multimillion-dollar research agreement.

UNIVERSITIES LICENSE A SUBSTANTIAL
AMOUNT OF FEDERALLY FUNDED TECHNOLOGY

During fiscal years 1989 and 1990, the 35 universities in our study (1) granted 197 exclusive licenses and 339 nonexclusive licenses and (2) earned \$29.3 million from exclusive licenses and \$52.7 million from nonexclusive licenses. Typical licensees given exclusive rights to commercialize the results of federally funded research were small U.S. businesses; and most exclusive licensees were pharmaceutical, biotechnology, or other medical companies.

Most of the surveyed universities substantially expanded their programs to transfer technology to businesses during the 1980s. Twelve universities formed an office to license technology, while many others expanded and/or reorganized their technology licensing activities. For example, Harvard University, which granted its first license in December 1980, granted 39 licenses in fiscal year 1990.

Relationships between licensees and universities are becoming increasingly complex. The 35 universities reported that (1) scientists who developed the technologies for the 61 exclusive licenses consulted for, owned a substantial amount of stock in, or

had other relationships with the licensees and (2) members of industrial liaison programs were granted exclusive licenses in four cases. In 12 additional cases, companies that had long-term agreements with universities to fund general research received exclusive licenses for technology they did not directly co-sponsor. None of these relationships are necessarily inappropriate; in fact, in many cases, they are necessary for commercializing the technology. However, the potential exists that exclusive rights to federally funded technology could be inappropriately granted because of undisclosed conflicts of interest or other relationships.

NIH AND NSF LACK STRONG CONTROLS OVER
INAPPROPRIATE ACCESS TO RESEARCH RESULTS

NIH and NSF, which spent \$5.8 billion for university research in fiscal year 1990, have general guidelines that rely on funding recipients to establish policies and procedures to resolve and report any potential conflicts of interest or other relationships. Neither agency requires funding recipients to submit their policies and procedures for review to ensure that they adequately address conflict-of-interest issues.

The 35 universities surveyed have established various policies and procedures to prevent inappropriate access to research results by businesses. Fourteen universities generally relied upon faculty and other members of their university community to voluntarily disclose a potential conflict of interest.

In contrast, 21 universities required that faculty and/or technology licensing personnel disclose outside interests or certify whether potential conflicts of interest exist at specified points. In particular, of the 21 universities, (1) 16 required faculty who are principal investigators to certify in writing whether any potential conflicts of interest exist as part of the

approval process for sponsored research projects, (2) 9 required that some or all of their faculty annually disclose outside interests, and (3) 14 required that technology licensing office personnel annually disclose outside interests or certify whether a potential conflict of interest exists. These procedures increase the likelihood that potential conflicts of interest will be disclosed, allowing the universities then to decide how best to resolve and/or monitor any such relationships.

In response to the growing involvement of businesses in university research, both NIH and NSF are considering alternatives to strengthen their guidelines for universities and other funding recipients to better, and more uniformly, control potential conflicts of interest in the conduct of research. In December 1989, after an early attempt, NIH withdrew proposed guidelines that would have restricted interactions between grant investigators and businesses in response to many commenters' strong concerns about their effect on university-industry relationships. NIH is again planning to promulgate a regulation by publishing a Notice of Proposed Rulemaking in the Federal Register for public comment. NIH's Associate Director for Extramural Affairs indicated that the proposed rule is likely to retain the requirement that all investigators and other key personnel involved in NIH-funded research disclose certain types of outside interests before an award is made and annually thereafter. In addition, NIH is considering whether to prohibit investigators and other key personnel for clinical drug trials from having any financial relationship with a business whose product is being tested.

On July 16, 1992, NSF issued a notice of proposed changes in the Federal Register that would require faculty members, investigators, and professional employees at grantee institutions who are involved in NSF-funded research and educational activities to disclose certain types of outside interests before an award is made.

CONCLUSIONS

Growing interactions between universities or nonprofit research institutions and private companies increase the potential for conflicts of interest or other relationships that might give a particular company inappropriate access to, and therefore an unfair advantage in commercializing, the results of federally funded research. Requiring that investigators and other key personnel disclose certain types of outside interests as part of the grant award process is an essential first step for improving a grantee's management controls over potential conflicts of interest. Accordingly, our May 1992 report recommended that both NIH and NSF require their grantees to have procedures in place to effectively manage potential conflicts of interest and that both agencies review their grantees' policies and procedures to ensure that grantees adequately address conflicts of interest. Both NIH and NSF have initiated steps to address these issues through the regulatory process.

With respect to the specific issues being addressed in the hearing today, we believe it is equally important that a recipient of substantial federal research funding--whether a university or a nonprofit research institution--notify and consult with NIH or other federal agencies before entering into any such major agreement that may give rights to commercialize resulting technologies to a particular company if substantial federal funds are involved. In this way, the government can become aware of who gets access to and ultimately benefits from the results of federally funded research and take any appropriate actions to help ensure that the public's interest is protected.

Mr. Chairman, this concludes my statement. I would be happy to respond to any questions you or members of the Subcommittee may have.

**Statement on Academic-Industry Relations to Subcommittee on
Regulation, Business Opportunities, and Technology; United States
House of Representatives, Committee on Small Business**

Henry Etzkowitz

March 11, 1993

I am Associate Professor of Sociology at the State University of New York at Purchase. I am also Research Professor at the Center for Science and Technology Policy, Rensselaer Polytechnic Institute and co-director of the International Study Group on Academic-Industry Relations of the Science Policy Support Group, London. My research on science and technology policy focuses on women in science and engineering, industrial policy and academic-industry relations.

I have studied academic-industry relations at three levels: university scientists as organizers of research groups and companies, the role of the university in commercializing research and the activities of state governments in promoting science-based economic development. During the past ten years I have personally interviewed more than 200 scientists, academic administrators, corporate and state officials and examined archival sources at Massachusetts Institute of Technology and Stanford University, among others. The National Science Foundation has supported this work through its programs on Ethics and Values Studies, Science Resource Studies, Sociology, Regional Science and History and Philosophy of Science.

1. Overview

A larger number of universities in the United States are now attempting, with more or less success, to become research universities. Twenty or thirty years ago the discussion was about expanding from a dozen to twenty or thirty full scale, high quality, research universities. Recently, the bulletin boards of the University of Massachusetts at Boston, an institution that is not generally known as a research university, carried notices of a talk given by the Vice-Chancellor entitled "400 Research Universities?" The clear inference was that if there is the possibility that the United States could support 400 research universities, then there is a role for the University of Massachusetts, Boston as a research university. Certainly it would not be a research university primarily oriented towards traditional disciplines. University of Massachusetts, Boston's areas of growth to the Ph.D. level are targeted to meet regional needs. For example, an environmental science Ph.D. program has been initiated, with a special focus on Boston Harbor. The major universities in the Boston region such as MIT and Harvard do not offer advanced degrees in this field. Thus, the growth strategy for many emerging research universities is to determine areas of regional need where corresponding local sources of support can be identified.

Similarly, economically depressed areas look to research universities to supply new science and technology to revive an existing industrial base. For example, in the early 1980's, most of the forestry school at the University of Michigan was eliminated with one hand, and with the other, the money came back to the university to establish a new Center for Robotics Research. A consortium of the business, political and academic leaders in Michigan had decided upon this strategy to revive the technology of the American automobile industry. The concept was to set up a research center, drawing upon the faculty of the University of Michigan and other universities in the area. Thus, we have the establishment of research centers designed to feed into the local economy.

The public has also revalued its view of science. In regions where a high technology economy has emerged from campus based research, the public expectation in the midst of decline is for a

new wave of technology to emerge from area academic institutions. Thus, a television editorial commentator looking at the bright side of the Massachusetts economic decline stated that,

We have world class universities poised to turn scientific talent into marketable products

¹ It is interesting to note that science is viewed not only as the source of new economic goods but universities are looked to for the entrepreneurial leadership to transform potential into practice. This public perception is, of course, based on more than a half century of university-industry interaction that revived the New England economy once before. Indeed future expectations are supported by several hundred million dollars of public investment in biomedical and biotechnology research facilities adjacent to Boston's medical schools and universities².

2. Entrepreneurial Science

From the formation of the research university in the late 19th century to well into the post World War II era university-industry relationships were largely established at the behest of industry to serve the needs of existing companies. Engineering schools reorganized themselves to serve the research needs and supply personnel for the growing science based electrical and chemical industries. The linkages included cooperative programs which sent students to industry for part of their training, university professors undertaking research at the request of industry and donations of money and equipment by industrial firms to support engineering education (Noble, 1976:chap.7). The relationship between university science and business was well established by the 1920's. A contemporary survey showed that 29% of the 600 industrial firms queried were supporting some form of cooperative research program including university connections (Kimball, 1929). University-industry relationships declined in the 30's due to constriction in funding (Servos, 1980) and became relatively less important in the post war era with the growth in government funding of science.

The current resurgence of university-industry relations is due to a decline in government funding of biomedical sciences, changes in federal regulations transferring control of patent rights to government funded research to the universities and scientists interest in commercializing their research results. The new university-industry connections include universities establishing research parks, university scientists involvement in firms e.g through membership on advisory boards, boards of directors, stockholding in exchange for consultation services, assumption of managerial responsibilities and involvement in the formation of firms. The older forms of university-industry connections involved payment for services rendered, whether it was received directly in the form of consultation fees or indirectly as endowment gifts. The new university-industry relationships involve the multiplication of resources through the university's and faculty members participation in capital formation projects such as real estate development and formation of firms.

The industrial relations of academic science have a long history but until recently these activities were largely confined to land grant universities, a science and engineering based university like Stanford, and to a unique technical institution, MIT. Entrepreneurial activities are currently taking place in a broader range of research universities, including those that emphasize the liberal arts. Indeed such activities are often encouraged by government even as they are sometimes a matter of dispute within the academy. Conflicts have erupted such as the one at Harvard in 1980 when the administration proposed that the university participate financially in a firm based on the research of one of its faculty members. The ensuing debate rapidly escalated into a controversy over the goals of the university, the conduct of science, and the professional ethics of scientists that only abated when the plan was dropped. Even as President Bok declined to commit the university to participate in the establishment of a firm based on a faculty member's research, he stated that he would explore other means of involving Harvard in

¹Editorial, Boston ABC Affiliate, evening news, July 27, 1990

²Boston Globe July 25, 1990

realizing financial gain from campus based research. In 1988, a joint venture involving the medical school was announced. Although the *New York Times* questioned whether traditional academic values were being abandoned, there were no reports of on campus opposition as there had been eight years before.

During the intervening period, similar proposals have become accepted practice at other universities. For example, the University of Colorado accepts equity in faculty formed firms; Washington University, St. Louis and MIT take the role of venture capitalist and Harvard has participated in ventures through its corporation. These actions represent involvement of the university in the transformation of knowledge into intellectual property and its subsequent capitalization and transmutation into factors of production. Eschewing the ideal of knowledge for its own sake, in practice if not in ideology, academic scientists and universities are becoming more involved in translating knowledge into economic goods. Such practices have implications for the relationship of academia to society, the normative structure of science and for the legitimation of knowledge producers as socially, as well as culturally, important personages.

Academic science has become increasingly entrepreneurial, not only through connections made to business firms for research support or transfer of technology but in its inner dynamic. As we have seen, it is the institutional imperative to raise funds to support a research group that is the underlying driving force of entrepreneurial science. Science, even most "little science" is a group activity that requires support. Eventually research support must be paid for and in a capitalist society "knowledge of nature for its own sake" is an insufficient legitimation to support an enterprise requiring large scale funds such as the scientific enterprise. As government support for research becomes more stringent and military requirements for science recede, economic contributions become the basis for a restructuring of the scientific enterprise. Although industry funding of academic science declined during the early post-war era, it was the decline in federal funds for academic research in recent years that has made university-industry relations salient again. But that was only the proximate cause. The research base established with federal funds at leading public and private research universities contained a wealth of only partially tapped knowledge that it was believed could be translated into economic development. In the face of competitive pressures on United States' industries, university based research became the key to a strategy of renewing regional industries or growing new firms through establishment of relationships with nearby university laboratories.

Academic scientists have a long history of working with industry, having helped establish the early industrial research laboratories in the United States. Until quite recently most university-industry connections separated academic and commercial practices. Limits were placed on how much time an academic could devote to outside concerns. A one fifth rule allowing one day per week became commonplace. Even as ongoing relationships, consulting arrangements were usually conducted apart from academic research, although based on the academic's expertise accumulated from campus based research. Consulting relationships typically involved brief visits to industrial sites or conduct of discrete projects on university premises. A consequence of this separation was that it left control of commercial opportunities of academic research in the hands of industry whereas control over the direction of research and choice of research topics was left to academic scientists. Although regular payments were made to individual consultants, the large scale transfer of funds from industry to the university was left up to the generosity of companies. Thus, the traffic between university and industry was policed so that boundaries were maintained even as exchanges took place through consultation and philanthropy.

3. University-Industry Linkages: The Second Revolution

As late as the 1930's, most academics rejected government funding of research despite the ravages of the depression, fearing that the university would be unalterably transformed and autonomy lost. Indeed, the university was soon transformed and a new status quo created in which the autonomy of the academic enterprise became identified with government funding procedures that a new generation came to view as traditional during the post-war era. Today, universities are undergoing a "second revolution". The first academic revolution, taking off in the late nineteenth century, made research a university function in addition to the traditional task

of teaching. The second revolution is the integration of economic development into the university as an academic function along with teaching and research. University-industry relations in the United States have evolved through three stages of: marketing, generating and capitalizing intellectual property.

3.1. The First Stage: Marketing Intellectual Property

The generation of profits from university research initially took place through the use of the patent mechanism. Established in the United States Constitution to protect inventors and to encourage technological innovation, universities also cautiously began to file patents for faculty research. It was already evident early in the twentieth century that discoveries made in research universities could be financially lucrative as well as scientifically and medically significant. For example, Banting and Best, the discoverers of insulin turned over the rights to their research to the University of Toronto, establishing the precedent that the research of faculty could accrue to the financial benefit of the university. Such individual cases established the precedent that university research could be patented.

The next step was the founding of organizations inside and outside of the university to market patent rights and bring university research to a higher stage of development and thus achieve greater commercial salability. led to the establishment of formal linkages between the university and industry. For example, the Alumni Foundation of the University of Wisconsin marketed patents derived from academic research to industry and financed faculty research projects with the monies made. These funds enabled Wisconsin to become a major research center in biology in the 1930's and 40's. Other universities adopted this model in the 1940's and 50's, and it is being looked to again, at present, as a means to finance the universities.

Established as an independent entity to mediate between the academic and business worlds the Research Corporation specializes in conducting the additional research often needed to make a patentable discovery into a marketable one. The Corporation was founded in the 1910's, with funds generated from the donation of the "precipitator", a pollution control device invented by Dr. Frederick G. Cottrell, a physical chemist. Professors recommend inventions and the corporation also has its own staff members ferret out marketable discoveries. The most promising are patented and the royalties divided between the university and the Research Corporation in a 6-to-4 ratio. Profits go to a research grant program that funds scientific research in the universities. The Corporation is still in operation although it is not as significant a factor as it was before individual universities took on the tasks of technology transfer themselves. Recently, many universities have established their own offices to patent, license and market intellectual property generated on campus.

3.2. The Second Stage: Generating Intellectual Property

The second stage is based on the development of group research within the university. While the individual scholar pursuing his or her research is still the predominant mode in the humanities, in the physical and biological sciences and to a considerable extent in the social sciences the increases in productivity that can be attained through the division of labor has led to more organized modes of research. Organized research units in the United States date to the establishment of Agricultural Experiment Stations, first in Connecticut, and then in several other states during the Jacksonian era. The Hatch Act of 1887 provided federal resources to expand existing agricultural research organizations and to establish stations, typically affiliated with land grant universities, in states that had none. These units, with their applied research focus, contributed to the development of what was then the nations' most important industry.

In the early 20th century, loose interpretations of earlier more formal German academic models of organized research appeared in the basic sciences in the emerging research universities of the United States. Faculty and students began to work together on research projects, typically after the achievement of a secure methodology in a field. United States academic science has been transformed into a more organized mode, closer to industrial lab formats during the post-war era. The model of the professor supervising a few Ph.D. students in one-on-one meetings

has largely been relegated to the humanities. In most of the sciences the so-called individual investigator is the leader of a research group comprising some or all of the categories of B.A., M.A., Ph.D. students, post docs, research associates and technicians. The professor has become the fund raiser, personnel manager, publicity agent and research director of a team of researchers. These groups operate as firm-like entities or "quasi-firms" within the university, lacking only a direct profit motive to make them a firm. When professors move outside of the university to form a firm, their academic experience as entrepreneurs often stands them in good stead. They negotiate with venture capitalists instead of research agency program managers, hire employees instead of recruiting students and post docs. This is in contrast to an earlier generation of technical entrepreneurs and firm founders who were viewed as bringing only technical expertise to a new firm, lacking the managerial skills and entrepreneurial background of many contemporary academic scientists. Indeed the holder of a professorship at a major university has been held to be the equivalent of the president of a medium sized corporation, in managerial experience.

According to a recent estimate there are some 7,000 organized research units at United States universities, largely supported by federal funds.³ Until quite recently, federal grant requirements mandated that patent rights be retained by the federal government. Since such a large proportion of university research was federally funded there was a gap in the transfer of knowledge to industry as the federal government did not undertake to market its patent rights and the mechanisms that had earlier been developed to market such rights were precluded from arranging the sale of federally funded research. This situation changed radically in 1980 when the federal government, wishing to spur technological innovation in response to increased international competition, allowed universities to retain patent rights to federally funded research. This new rule placed the universities in control of vast amounts of potentially marketable research. The leading federally funded universities quickly moved to establish internal rules to gain control of such discoveries and established offices to coordinate their sale. Thus, the expansion of group research and the change in the legal status of government funded discoveries greatly enlarged the base of capitalizable knowledge in the universities.

3.3. The Third Stage: Capitalizing Intellectual Property

The existence of organized research units also made possible new forms of arrangements among corporations, governments and the university. Moreover, the research groups themselves, having many of the characteristics of firms, sometimes attained independent status of spunoff new entities. Industrial contracts, state initiatives and formation of firms have become the preferred mechanisms for capitalizing knowledge, although the older practices for dealing in patent rights have also been revived.

3.3.1. Industrial Contracts

The existence of research groups within the university allowed new funding techniques to be developed that essentially traded patent rights for research support. Until quite recently, corporate funding of university based research usually took place in the final stages of a research program when practical results were forseen but not yet realised. In this model, when a university researcher achieved a potentially useful result, the company would undertake development research in its own laboratory. If a sufficiently profitable product could be developed, manufacture and marketing would follow. The university and the investigator would be paid royalties according to an agreed upon rate.

The university's medical school model of the clinical professoriat is being applied to the research faculty as well, enabling distribution of income to be controlled by the university. Clinical professors turn their income from patient fees over to the university. The university redistributes this income, reserving part of it for the operation of the medical school and its

³Herbert Fustfeld, The Technical Enterprise Cambridge: Ballinger 1986

research programs and returning another part of it to the clinical professors in the form of high salaries. The research faculty were traditionally supported, in part, by the income generated by the clinical faculty. Now the activities of the research faculty are expected to generate even larger amounts of funds than was possible through the practice of medicine. It remains to be seen whether the role of clinical professor will be more attractive to research faculty than the role of entrepreneurial scientist. On this decision, rests the ability of the university to cement its alliance with major corporations, effecting the transfer of technology under their auspices rather than that of a professor managed firm.

For example, the now defunct agreement between the Monsanto Corporation and Washington University provided 23.5 millions for research in a specific area, the study of proteins and peptides in cells. These funds were made available, over a five year period to the university's medical school. A review committee, representing the faculty and Monsanto scientists, disbursed the funds. Faculty members submitted research proposals to the committee in the areas of investigation specified by the agreement. Research results of interest to Monsanto were controlled by the corporation, with provisions for publication rights. Any economic return was split among the corporation, the investigator and the university.

Monsanto had similar agreements with Harvard and Oxford Universities. The company recently ended the agreement with Oxford early, paying a ten million dollar termination fee. The Monsanto experience appears to support those observers who suggested that these large contracts were a temporary phase in academic-industry relations; that as soon as companies learned the new techniques they would move the research in house. However, as the Subcommittee is aware Sandoz has replaced Johnson and Johnson at Scripps. The overall trend is for an increase in company support of research in universities. R&D sponsorship multiplied almost 5 fold in US from 1977 to 1987. In the U.K. the rate has more than doubled from 1984-89. These growth rates in both countries are considerably in excess of that for total business R&D spending.⁴ Within this picture, foreign companies with longer time perspectives may have greater staying power than American companies. When Sandoz bought a stake in Genentech they instructed the company to continue its long term research that was about to be cut under financial pressures. Many foreign companies also have a greater ability to take advantage of university programs to allow company researchers to participate in academic labs. In interviews that I conducted at MIT, for example, research centers found that they had to develop less intensive methods of linkage such as occasional meetings due to the reluctance of U.S. researchers to leave their company site.

Large contracts are of great interest to universities since research capacities are in place that are difficult to sustain, let alone expand with federal funds. Rights to intellectual property are seen to be a small price to pay to assist underfunded researchers to sustain their laboratories and to encourage well funded investigators to modestly expand their research efforts. Some observers hold that these large contracts are a preferable form of academic-industry relation on the grounds that they are least disruptive to traditional academic practices, with their procedures for peer review etc. They have the potential effect of limiting faculty entrepreneurship. According to Vice president Guze, "A major feature of the Monsanto-Washington University agreement is the deliberate plan to limit entrepreneurial efforts by faculty beyond those that already exist to obtain grant support for the faculty members' laboratory or program". Guze argued that prohibition from individual involvement in commercial ventures will keep the faculty attuned to its "...academic commitments and priorities". On the other hand, Sandra Panem, Director of the Solomon Brothers Biotechnology Fund argues that spinoff firms are the best technology transfer mechanism.⁵ Through a new firm, the people most closely involved with the new technology stay with it as it is brought to fruition rather than passing it on to a different group in a large firm. Of course, most new firms eventually link up with large companies for

⁴Jordan Lewis Partnerships for Profit: Structuring and Managing Strategic Alliances New York: Free Press, 1990 p.79

⁵Talk to Sloan Science Policy Breakfast, New York City, February, 1993.

testing and marketing.

4. Formation of New Firms

The attempt to institutionalize the 19th century German model of a single professor representing a discipline, surrounded by a permanent staff of assistants, introduced into Johns Hopkins and the University of Chicago in the late nineteenth century, was soon replaced by a departments with relative autonomy of professors of different grades. In academia, professors are expected to be team leaders and team members, with the exception of technicians, are scientists in training. An Assistant Professor in a United States university has considerable ability to set research direction, especially if he or she can convince an outside funding source. Excepting a few fields such as high energy physics heavily dependent upon instrumentation to which access is limited, a determined academic can maintain an independent research program in out of favor fields by carrying on research as a supplement to teaching. In industry a change in research direction can be mandated by superiors although a project can often be carried on "under the table" for a considerable time, for example the superconductivity research in IBM's European lab that eventually resulted in a Nobel prize.

Instead of developing a separate set of research institutes as was the practice in Europe, basic research was located in academic institutions. Professors, already paid for teaching duties, assumed research responsibilities, as well. With modest financial support, graduate students assisted the professor at the same time as they received their training. This system was productive and cost effective due to the low-rates of pay and the high level of results obtained, but because of the flow of people through the system. Students entered the laboratories and left with their degrees within a relatively few years. A continual stream of new people brought in new ideas in contrast to the institute model, a more stable structure, where ossification can easily set in unless there is a continual expansion of the institute bringing in new people. And that, of course requires a much higher level of funding.

In between "big science" represented by institutions such as CERN and "little science" of the lone scholar is the mid-sized research group headed by a so-called individual investigator. These are typically professors who are supporting at least a post-doctoral or two, several graduate students, even some undergraduates, and even at the secondary schools-- a middle-sized research team. For an assistant professor who has three or four people, an associate seven, and then for a full professor, up to fifteen or twenty persons in some areas of science. At the lower end of mid-sized science, an investigator is working at the level of between one hundred and several hundred thousand's of research funds, typically with a main grant from a single agency such as the National Institutes of Health, and perhaps a secondary grant from an additional agency.

The organization of these groups changes as the size increases to about seven or eight members. The professor who formerly was at the bench doing research is typically compelled to remove themselves from the bench to devote virtually full time to organizational tasks. At this level, the investigator primarily spends time:

- fundraising and proposal writing;
- going to conferences to make new contacts and to announce results of the group;
- recruiting new group members and handling the personnel problems of old ones;
- writing and reviewing articles;
- serving on review panels;
- managing the intellectual direction of the research from his or her office.

Such groups, where the professor is no longer primarily a researcher, have taken on the characteristics of a "quasi-firm". The professor has become a research manager at this scale, even though still an academic. This is not done from a profit motive, of course, but the group leader's

tasks have become largely organizational in nature. Often persons in this situation describe themselves as "running a small business" since they see themselves as responsible, not only for their own funding but for that of several other people. They must maintain the funding of their assistants in order for their research to continue at a competitive level with their peers. If they are in an academic department of a liberal arts university, their salary is guaranteed, but if they are in a medical school, even that must be raised. Having attained an organizational momentum, it is extremely difficult to function again as an individual researcher (Vollmer, 1962).

Occasionally, in the nooks and crannies of the experimental science departments of a major research university, sometimes literally in an attic, an individual can be found who is working by him or herself, typically in an unfashionable specialty, but this is now a very unusual circumstance. And so while the notion of the individual investigator is deeply embedded in grant proposals and in the ideology of academic science, the so-called individual investigator is actually operating as a manager, as an organizer of a group, and feels that he or she must sustain that group if they want their research effort to survive. In this system what typically happens under conditions of financial stringency? When funding gets tighter; then the scores on proposals to granting agencies must get higher in order to obtain a grant. To keep the level of research going at a pace of quality and quantity in order to sustain support, an investigator's productivity must go up as the competition increases. One strategy to improve productivity is to expand the size of the research group. The investigator with three or four assistants feels compelled to expand to five or six. If seven or eight was the norm, then the investigator has to break through the scale barrier, leave the bench, and go to nine or ten or even fifteen or twenty.

To expand the research group, the investigator must then seek additional grants. Instead of operating with the support of one or two funding sources, the investigator must start cultivating additional agencies. If the relevant federal agencies have been exhausted, then the investigator must look for a foundation and then beyond the foundation world and other traditional sources of research support to new streams of funding. State and local governments, for example, are often willing to provide research funds to improve the competitiveness of regional industry. The investigator might also engage in collaborations with colleagues from other disciplines and universities to approach new programs in the National Science Foundation with funds for interdisciplinary research centers related to industry. Alternatively, he or she might attempt to move from running a quasi-firm to an actual firm by participating in the organization of a company that will support research but with the intention of making a product and a profit.

It is usually not the intention of the professor who founds or helps initiate a science based firm to leave the university and become a full-time entrepreneur. Typically the goal of most academic entrepreneurs, once the firm is underway, is to participate in research as a consultant to the firm and play a role in policy making as a member of the board of directors. Some academics also wish to provide a site for their graduate students and post-docs to be consultants to earn extra monies. They believe that this opportunity will help their research group to be financially competitive with other universities in it's ability to attract graduate students and post-docs or expect that their assistants will find consulting opportunities in a colleague's firm to avoid the appearance of a conflict of interest. In the long term the hope is that the firm will produce a successful product and that it's stock will become valuable. In this event it is expected that there will be a return of funds from the firm to support the professor's research group. That is typically what academic scientists say is their long term goal when they get involved in the founding of a firm. Of course they are interested in making money personally, but also express their motivation in terms of a desire to find a stable source of support for their research. Thus, at the level of the investigator, funding constrictions cause an increase in competition leading to the seeking of alternative sources of support. Under these conditions, some research groups will decline in size or even close. However, others will increase their size by drawing upon an expanded range of sources of support, resulting in overall growth of the academic research system.

5. Changes In Academic Policy

Some kinds of scientific and technical knowledge produced in the university (e.g. molecular biology, artificial intelligence and semi-conductor physics) have been redefined as intellectual property with commercial value. The capitalization of this knowledge to create new firms and to channel a flow of research funds from existing firms into the university is changing the purpose of the university, making it an engine of economic development as well as a vehicle of socialization, cultural memory and research. A new element has been introduced into the relationships between university administrators and faculty members. It has become recognized by its detractors as an unwanted element of the contemporary university scene and by its proponents as a means to revive the research university. University administrations have put in place policies and programs to market the research of their faculty and adjust these policies to retain the loyalty of faculty. Faculty members in fields with commercial potential such as computer science take into account the university's patent and time policies in their decision to accept or retain positions.

A number of universities have established committees, representing faculty and administrators, to respond to the problems and opportunities created by entrepreneurial science. Such committees are institutional mechanisms of normative change and constitute a strategic research site to examine how different viewpoints are expressed and mediated. Their task is to translate "ambivalence" into "confluence." These committees are arenas in which representatives from different social locations in the university interact under conditions where they share a common charge to produce a position. It is often believed that modest changes in university rules will allow commercial activities to be undertaken without endangering values. However, the process of conflict resolution in committees often leads, even those most highly opposed to normative change, to allow changes in rules to be made. Committee leaders produce rationalizations to show how old norms are not violated by new forms of behavior, thus laying the foundations for normative change. Acceptance is gained through reinterpretation of values or through concessions to interests e.g. increased financial support for the humanities from revenues accruing to the university from industry. New forms of behavior are then allowed, e.g. temporary withholding of research results as patents are sought, while traditional values are upheld.

To prepare the way for normative change, through committee process, alternative postures toward varying levels of entrepreneurial activities are considered. At the University of Chicago, a committee with apparently no actual instances of entrepreneurial science to deliberate about, role played responses to hypothetical cases. At a university, where the level of reality testing is higher with respect to commercialization of research, a calculus of time sharing between academic and commercial pursuits has been elaborated. Instead, of a relatively vague "one fifth" allowance for outside pursuits, a number of days per semester has been specified with precision. At another university exclusive licensing of university based scientific discoveries, in certain circumstances to companies has been agreed upon. University administrators await an open instance of firm formation, by a professor, to test the resolve of committee members to adhere to their provisional absolute prohibition against such activities.

A review of the guidelines and patent policies of several major research universities (Columbia, MIT, Yale, Stanford, Harvard, University of Chicago, N.Y.U., Cornell and Princeton) and a related institution (Massachusetts General Hospital) suggests that these institutions wish to strike a balance between traditional goals such as openness of research and gaining financial support from industry. There is some variation among the universities in their attitude toward patents, ranging from deferral to the faculty to complete control by the university. However, most institutions retain control of inventions developed on their premises while sharing benefits with faculty who were responsible. Some engineering faculty at Columbia were outraged at the attempt by the university to control their involvement with industry.

The major expressions of concern with the proposed guidelines came from engineering faculty who argued that it would result in the creation of a new bureaucracy that would impede communication with industry. Although no-one opposed sharing rewards with the university

some were adamant about not being allowed to accept stock and make consulting arrangements at their discretion. These faculty wished to maintain their status as independent entrepreneurs and not be superseded by the university as an entrepreneur. For example, a professor of Chemical Engineering characterized the new policy as both vague and restrictive. By giving the university control over patent rights it would create an inequity between copyright, left to the faculty and patents. He believed it would make the faculty into industrial laboratory employees and noted that "The university scientist, however, is unique among the members of the faculty. He raises the funds for his equipment, and from his research grants pays for the operation of his laboratories, the operation of the libraries and computers, and the stipends of his students. It is a gross exaggeration to imply that the university materially invests in the research of its faculty; the University operates its laboratories as profit centers."

They objected to the University getting involved in business while desiring to protect their right to do business under academic freedom. Other justifications included competitive pressures from other universities and industry, affecting Columbia's ability to attract faculty if their free access to consulting and other commercial arrangements were impeded. The University of Chicago expressed interest in having faculty enter into relations with industry including firm formation by faculty. Lacking real instances the university committee discussed hypothetical instances of industrial connections. While concerns were typically expressed by committee members over faculty allocation of time to external interests and loss of allegiance to the university the preponderant concern was to find ways to encourage such involvements in order to legitimate the university to the larger society on grounds of contributions to its economic development.

Guidelines of conduct and organizational mechanisms to market patents were all oriented to encouraging faculty to become more aware of the potential economic value of their research where such interest was low and to channel the translation of research into marketable products in ways acceptable to the university among faculty where interest in economic outcomes of research was high. All of these responses auger a shift in the direction of the research university and its members toward new normative patterns regarding the pecuniary content of knowledge. Whether built into organizational entities that handle the marketing of research, structured as guidelines for desired behavior or felt as enticements from the outside world: a new normative structure is emerging in the research university. They are norms in the sense that they push behavior in a clear direction with recognizable and consistent outcomes, enticing it where possible, coercing it where necessary.

6. Industrial and Science Policy

Despite the lack of an explicit national science and technology policy in the United States, one is created through pressures on government to develop research in certain areas. The ideology of the free market restrains the state from intervention in the economy. Nevertheless, ideological restrictions can be overcome by overriding purposes. Historically, three such purposes have been recognized in the United States: support of agriculture, the military and health. A fourth---contribution to industrial economic development---is in the process of becoming accepted although not without considerable resistance. Agricultural research targeted to improvement of particular crops also supported the development of theoretical work in genetics in the 1930's. Scientists successfully argued that this work would lead eventually to improvement in crops and at the same time they maintained their more immediate research projects. That research was then available to be translated into the economy.

6.1. Agriculture

The initial intervention of the state in the economy though the support of research took place in the mid-nineteenth century as a result of political pressure from a social movement of scientific farmers. These farmers believed in the application of science to improve agricultural production. A few attempted this individually, including President Jefferson who maintained test plots on his estate in Monticello, Virginia. But most farmers realized that they could not undertake the necessary research individually and through their local organizations pressured state

governments to establish agricultural experiment stations. Eventually their political pressure was felt at the federal level of government. But as in most cases of successful pressure for state intervention in the economy in the United States the activity was not undertaken directly by the federal government establishing institutes for agricultural research. Rather, in deference to free market ideology, the federal government contributed along with the states to the support of agricultural research units established at universities in each state. This is a model of decentralized centralization typical of state intervention, not only in the economy but in social welfare and other non-traditional state activities.

For the agricultural sector that relationship with government was established in the early nineteenth century. A first and fundamental point is that the ability to capitalize knowledge is based upon the existence of a considerable amount of research within universities. So if universities are solely teaching institutions the possibility for industrial relations is much more limited. It is largely confined to the traditional forms of provision of trained persons and perhaps some consulting. This was the way in which university-industry relations were conceptualized in the United States from the mid nineteenth century almost to the mid twentieth century, with the exception of a small number of institutions such as MIT, Stanford and the engineering schools of a few other institutions of higher learning. These schools invented the formats and set up the models which were later copied by others and generalized.

The ideology of the United States is that with respect to the economy it is business that is supposed to be the actor, not government, not the universities. Under what conditions is this ideology violated? It is violated when there is considered to be a higher national purpose that overrides the ideology. It was first violated in the area of agriculture in the mid-nineteenth century. Agriculture then was small farmers; it was the nation's major industry. There was a strong movement among farmers who believed in the application of science to farming. Individual farmers themselves, although some of them would try experiments, exemplified by President Jefferson who in his retirement had test plots on his estate and carried out experiments. But most farmers realized that they could not do research effectively on their own.

A social movement of scientific farmers successfully pressured state governments to set up experiment stations to do agricultural research. As the movement grew it influenced the federal government to take action in this area. Since the ideology of government non-action is so strong; when government acts against this ideology it cannot do so directly but must do so indirectly and typically through another institutional form. This is what happened in the development of research in agriculture. Instead of federal agencies being set up to do agricultural research, federal funds, together with state funds, were given to the universities to conduct research and then to transfer the technology to the farmers.

When state intervention is desired, laissez faire ideology requires that state participation be indirect. In agriculture the federal government did not establish a national research institute. Instead the federal government contributed funds to match state government funds to support research units at state universities. These units were oriented to the agricultural specialties of their regions and research was directed toward improving local crops. Extension agents brought farmers problems to the attention of researchers and brought researchers solutions back to the farmers. Although the emphasis was on solving local problems and addressing immediate issues, academics also formulated longer term research programs, justifying them on the grounds of eventual contribution to local agriculture, while continuing to meet immediate needs. Thus, in the 1930's agricultural research units initiated fundamental research in genetics which eventually resulted in hybrid corn.

The model was a form of decentralized centralization. It partially satisfied the requirements of ideology while allowing government to accomplish a purpose called for by the outside actors to the government, in this case a movement of farmers which were then the most powerful political force in the country. So the first buildup of research in the universities that was transferred into the economy is in the area of agriculture, dating to the mid and late nineteenth century. It is often noted that this is the basis of American strength in agriculture. This then led to, by the 1930's, into research in genetics. The original impetus to the research was applied, working on each

regions crops to make improvements. However, once these funds were provided to university researchers they were able to set their research direction. In mid-western universities many researchers decided to do genetics research that that would have an application to agriculture and also further their fundamental research interests. The university researchers set their own direction, justifying it with a practical application. They took off on their own ideas, not sticking to the narrow definition under which they were funded. In agriculture, basic research came out of the programs that were funded for applied research. This was the basis upon which a highly productive agricultural research and development system was created in the United States.

6.2. The Military

The next major intervention of the state in R&D took place at the onset of World War II. Leading academics including the President of Harvard James Conant and Vannevar Bush, quondam Vice President and Dean of Engineering at MIT and then Head of the Carnegie Institute of Washington convinced the government that academic science could be used to develop technology for the military. These academics successfully lobbied the executive branch of the federal government to found an agency to support research on military problems. Their goal was not to establish a government research institute but to use federal resources to support research at universities. Universities were not the obvious choice for locating such research. At the time, industrial research groups at major corporations had greater R&D capabilities. Academics had to be drawn together from campuses across the country to establish large scale research centers at a relatively few universities: MIT, Johns Hopkins, Berkeley, Chicago and Columbia. This resulted in a research build up at these universities in electronics, nuclear physics and other scientific and engineering areas relevant to solving military problems.

The government intervened to improve the technical base of military research by connecting it to the universities. Although the armed forces were satisfied that they could meet their own requirements for technological innovation, just before the U.S entry into World War II academic scientists and engineers who had worked for the military during World War I convinced President Roosevelt that the armed forces needed assistance. The Office of Scientific Research and Development (OSRD) was placed under the direction of academics rather than a government official or industrialist. Large scale laboratories that could be turned most quickly to military use were mostly in industry. But industrial scientists and engineers had not taken the lead in approaching the government. Industrial scientists such as Frank Jewett, the head of Bell labs took part, but in a secondary role supporting the lead taken by academics such as Bush and Conant. Since the research leaders who took the lead in this initiative were from the universities, they were placed in control of the agency established to carry out their plan and thus had the responsibility to dispense the funds allocated for the task. At that time no university, with very few exceptions, had large research centers with the ability to carry on research and development of weapon systems. The academic leaders of OSRD had to draw together researchers from universities across the country to a few sites to establish these capabilities.

The so called Rad-Lab at MIT and a few other laboratories were established at a half dozen universities. This resulted in a concentration of research in a few institutions, against the ideology both of government and of universities. The American academic system is highly decentralized with a multiplicity of institutions competing for funds of all kinds. Under conditions of military necessity, a few academic leaders were able to persuade their fellow academics to accept a concentrated system. Academics also agreed to accept federal research funds which they had refused during the 1930's even though the universities were starved for funds. During the depression efforts to persuade academics to ask the federal government for funds were defeated. It was against the ideology of both government and the academy. Again it was an overriding purpose, the exigencies of war that changed their actions. This led to a new format after the war to meet both the requirements of ideology and government; that is scientists opposition to government intervention. The separation of science from politics was made compatible with the expectation of government that research was useful through a peer review system, largely turning disbursement decisions over to academics within the confines of grant programs.

6.3. Health

The same story could be told of health. Medical research was also supported to meet military needs during World War II but the major impetus to the development of medical and biological research at universities in the past several decades has come from social movements and lobbying groups directed toward the cure of diseases. The health social movements to cure diseases, from cancer to heart to Alzheimers, support voluntary associations that fund research. These associations typically feel they are not able to raise sufficient funds to accomplish their goal. They exert political pressure to expand the federal role in health research. This has been accomplished by expanding the National Institutes of Health (NIH) and by supporting funding of health research at the universities. NIH existed from the mid-nineteenth century but on a very small scale. During the post war period the National Institutes of Health grew and multiplied through the efforts of social movements interested in curing diseases and using research to solve health problems. Research at the National Institutes of Health was greatly expanded and an extramural research program was established that has become the mainstay of research support for academic research in biology and related fields in universities and clinical research in the medical schools. Most of the diseases that the NIH was funded to cure are still with us but we have a biotechnology industry as an unintended side effect of the generous support of basic research.

7. Conclusion

What kind of interest should government retain in the funds that it disburses for academic research? In deciding to disburse funds through peer reviewed grants at NSF and NIH, government turned over considerable authority to the scientific research community. In recent years this system has been placed in a new context through an indirect industrial policy that both encourages and requires universities to commercialize federally sponsored research. This context can, of course, be further modified to accomplish public purposes in addition to the creation of new jobs and infusing existing companies with new technologies. Government can retain part ownership in the intellectual property that it has helped pay to create and direct those funds to support additional research or reduce the prices of resulting products.

Since small start-up firms are the most effective means of developing new technology and creating jobs, government can play a greater role in providing grants, through a civilianized DARPA and NIST, to the initiators of such firms. Certainly, large firms have an important supporting role to play in the commercialization of technology from academia. The Monsanto, Hoechst and Mallinkrodt agreements have been published⁶ with no noticeable adverse effects. If necessary, the disclosure of the terms of agreements which join together public and private funds for the conduct of research could be mandated in the public's interest of knowing how its monies are used. If the subcommittee's goal is to reduce drug prices, additional steps would likely have to be taken beyond retaining the public's interest in the intellectual property it has contributed to drug manufacture. For example, advertising could be replaced by a publicly maintained non-partisan electronic information system, perhaps organized by NIH. I thank the committee for the opportunity to provide background on academic-industry relations and would be pleased to discuss any of these points.

⁶See Bernard Reams University-Industry Research Partnerships Westport: Quorum Books, 1986

Testimony by

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On the Implementation of
the Bayh-Dole Act of 1980
by The Scripps Research Institute

Before the

Subcommittee on Regulation, Business
Opportunities and Technology

Committee on Small Business

United States House of Representatives

March 11, 1993

Mr. Chairman and Members of the Subcommittee:

The Scripps Research Institute (Scripps) appreciates this opportunity to present testimony on our implementation of the Bayh-Dole Act of 1980. I will be discussing the mission of Scripps, its funding arrangements in general and the structure of the agreement between Scripps and Sandoz in particular, and how Scripps' arrangement with Sandoz accomplishes the goals of the Bayh-Dole Act and preserves the federal government's prerogative to fine tune its policy objectives.

Scripps engages in basic research for the public benefit, and does not perform commercial drug development. Based on our experience to date, the Bayh-Dole Act has provided an effective and efficient mechanism for transferring the results of laboratory research at Scripps to the commercial sector. Moreover, collaborations with commercial companies have enhanced our own internal research capabilities through access to corporate funding, scientists, research programs, and, in some cases, essential biological research materials that would not otherwise be available to our investigators. At Scripps, such access has been managed so as to preserve academic freedom and ethical standards.

The Scripps Research Institute

The Scripps Research Institute is the world's largest non-profit biomedical research facility not affiliated with a university. Since its establishment in 1961, Scripps has become

internationally renowned for its basic research into immunology, autoimmune diseases, neurosciences, cardiovascular diseases, molecular biology and synthetic organic chemistry. Scripps has over 1500 employees, including 190 principal investigators, 390 postdoctoral fellows, 500 technicians and 400 administrative and support personnel.

Scripps is governed by a Board of Trustees that presently has ten members, six of which are "outside" trustees having no business or employment relationship with Scripps, two trustees are officers of an affiliated non-profit health care company, and two trustees are officers of Scripps. Trustees of Scripps do not receive compensation for serving as trustees.

Scripps Performs Basic Research, Not Drug Development

The mission of Scripps is to perform and foster peer-reviewed basic research for the public benefit. Such research at Scripps seeks to discover the fundamental principles and mechanisms of health, disease and medicinal chemistry. Translation of the results of that research into therapeutically useful drugs is "drug development," a capital intensive, high risk process traditionally undertaken by pharmaceutical companies. Drug development involves those applied research activities necessary for obtaining approval of a particular new drug by the FDA, such as analogue optimization, toxicity testing, formulation evaluation, clinical trials, and the like. Scripps has neither the resources nor the expertise to engage in all of

the activities necessary for the development of new drugs. Therefore, in order to translate research results into useful new drugs, Scripps must work with a partner whose drug development skills and resources complements Scripps' basic research skills.

This allocation of work and this "partnership" between Scripps and its commercial sponsors have worked very well in the past to move scientific discoveries from the research laboratory into the hospitals, pharmacies and homes of patients, all for the betterment of mankind. For example, on March 2, 1993, the FDA approved 2-CdA, a new drug for the treatment of hairy cell leukemia, a rare and often fatal cancer of the blood and bone marrow. Use of the drug was discovered at Scripps and subsequently developed by Johnson & Johnson (J&J) in consultation with Scripps.

Drug Development is a High Risk Enterprise

2-CdA represents the first therapeutic product developed and marketed by J&J under its agreement with Scripps. Yet, that achievement comes after providing more than 10 years of research funding to Scripps totaling more than \$125 million. While other drugs discovered at Scripps are in J&J's developmental pipeline, there are also numerous examples of drugs whose development has stopped because of technological barriers such as unacceptable toxicity, lack of specificity or unacceptable side effects. The experience at Scripps with its

corporate partners is that commercial drug development is a long term, very expensive and high risk proposition.

Current Funding

Scripps' 1992 budget of more than \$100 million is derived primarily from the National Institutes of Health (NIH) and other federal agencies. Scripps also receives a significant amount of research funding from corporate sponsors. Research funding obtained from corporate sponsors at Scripps falls into two categories: Specific Funding and General Funding.

Specific Funding is funding that must be used by Scripps to support a specifically identified basic research project as proposed by one of Scripps' scientists. Scripps accepts Specific Funding, in its sole discretion, and only for projects that are within Scripps' basic research programs and mission.

General Funding is funding that can be used in the sole discretion of Scripps to support the costs of any research at Scripps, without restrictions by the corporate sponsor. Typically, it is used to support the training and research of young scientists who do not otherwise have funding, to purchase state-of-the-art research equipment and to support research into some risky, but potentially fruitful scientific problems that would not ordinarily be funded by the NIH. It is General Funding that has permitted Scripps to maintain its position as an international leader in basic biomedical research. NIH-supported

researchers at Scripps benefit from General Funding supplied by corporate sponsors through access to equipment and research support programs whose costs are paid for through such General Funding.

Currently, Johnson & Johnson (J&J) and PPG Industries, Inc. (PPG) are the only corporate sponsors providing General Funding in exchange for licensing option rights to broad areas of research at Scripps. J&J has been providing General Funding to Scripps since 1982. PPG has been providing General Funding to Scripps since 1984.

Future Funding

Scripps expects to successfully compete for research funding support from NIH for so long as such funding is available to non-profit research facilities. In addition, to the extent that such arrangements are permitted by federal laws and regulations, Scripps intends to supplement the future NIH funding it receives with General Funding and Specific Funding from corporate sponsors.

For example, the agreement under which Scripps receives both General and Specific Funding from J&J expires at the end of 1996, almost fifteen years after its inception. Looking to the future, Scripps has negotiated an agreement under which Sandoz Pharmaceuticals Corporation (Sandoz), a Delaware corporation, has the option of replacing J&J as the primary corporate sponsor of basic biomedical research at Scripps for the years 1997-2007.

The Bayh-Dole Act Policies and Objectives

Prior to the Bayh-Dole Act, the individual government granting agencies were responsible for managing the transfer of technology from federally sponsored research to the private sector for development. This resulted in extensive delays, offered no incentives and provided limited protection to the technology. Evidence that it did not work is that Congress passed a bipartisan bill to implement the current policies.

With the Bayh-Dole Act of 1980 (the Act), Congress established guidelines to regulate the transfer of technology resulting from federally funded research to commercial companies for development into products. Under the Bayh-Dole Act, Congress permitted research institutions to retain the rights to any invention which results from a federally funded research project. Institutions electing to retain title to their inventions are required to seek patent protection for the invention, to promote its licensing for use as a commercial product, to share any royalties with the inventors, to provide that the products to be sold in the United States be substantially manufactured in the United States, and to protect certain rights in the United States Government to ensure that the invention finds practical application for the public benefit.

Thus, the applicable laws and governmental policies encourage research institutions to enter into contracts to commercialize technology developed through federal funding; and

those current laws and policies do not provide for the NIH to preapprove such contracts. The applicable laws and policies impose no restrictions on a research institute entering into an exclusive and comprehensive technology transfer arrangement with a commercial company, regardless of whether the company is headquartered inside or outside the United States.

The Bayh-Dole Act was passed in 1980 because the results of the basic science being funded by the federal government were not being effectively translated into useful products available to the public. In particular, the Bayh-Dole Act addressed the concern that new drugs were not being developed and new technology was going unnoticed and unused because it was difficult for pharmaceutical companies to obtain exclusive development rights.

The Bayh-Dole Act has decentralized the technology transfer process and provided exclusivity as an incentive, thereby stimulating tremendous growth in the biotechnology industry. The emergence of many new diagnostic and therapeutic products is a direct result of the Act. In addition, the Act has produced an abundance of intellectual properties, many of which are, or hold the promise of being, the central major asset of new, competitive businesses.

Benefits to Scripps Under the Bayh-Dole Act

The Bayh-Dole Act has helped Scripps to perform its mission in a number of significant ways, all of which are

predicated on the right to retain title to, and grant exclusive licenses for, discoveries made at Scripps. For example, without corporate sponsors, the life-saving treatments discovered at Scripps for hairy cell leukemia and hemophilia would not be available to the public today.

The Bayh-Dole Act has given Scripps access to significant amounts of non-governmental funding for basic research. That funding has been used to train many young scientists. It has also been used to purchase state-of-the-art research equipment and facilities, thereby enhancing NIH funded research at Scripps. The corporate relationships fostered by the Act have also given Scripps' scientists access to the scientists and research programs of the corporate sponsors. In some cases, corporate relationships fostered by the Act have provided Scripps' scientists access to essential biological materials that would not otherwise be available to academic researchers.

It should also be noted that the licensees of Scripps technology reimburse Scripps for patent costs; and such costs amount to millions of dollars a year. Those are dollars that Scripps would not have if it were not for its licensees. Without such patent protection, no commercial company would spend the millions of dollars necessary to develop the new drugs discovered at Scripps.

Technology Transfer at Scripps is Diverse, Not Monolithic

Scripps monitors the production of new technologies created through its research programs for significant developments that may be of interest to commercial companies. Scripps usually elects to retain title to, and seeks patent protection for, commercially significant developments it identifies.

While J&J and PPG presently have broad option rights to license new technologies at Scripps, they typically only exercise those rights for technologies having a potential market size appropriate for a large corporation. Furthermore, even large companies like J&J and PPG have limited funding for development and strategic plans within which such funding is spent. To maintain a license for technology from Scripps, a company must be actively developing the technology, a process that requires spending development dollars.

J&J, PPG and Sandoz have all acknowledged that Scripps produces more new technologies than any one of them alone could effectively develop, let alone afford to develop. In addition, Scripps' basic science endeavors produce new technologies outside the scope of the strategic plans of each of those companies.

Thus, Scripps is constantly presented with opportunities to license technologies to companies other than J&J and PPG. There is no evidence that that situation will be different once Sandoz replaces J&J at Scripps. Such licensing has been, and will be, done on a competitive basis.

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Presently, approximately 100 technologies at Scripps have been excluded from the J&J, PPG and Sandoz research funding agreements. Scripps either has licensed or is seeking to license those technologies, and future research related thereto, to other companies.

By contrast, J&J represents to Scripps that it is using reasonable efforts to develop 62 therapeutic and 23 diagnostic technologies licensed from Scripps.

Therefore, to say that one or two companies are reaping the entire benefit of all of the federally funded research at Scripps is not accurate. Scripps feels that some diversity is healthy and has sought to preserve it in all of its corporate relationships.

Structure of the Sandoz Agreement

It has been the overwhelming experience at Scripps that exclusive licensing of rights to many of the inventions made at Scripps is the most effective and efficient means for developing practical applications of those inventions for the public benefit. Therefore, in exchange for significant research funding and royalty payments from future sales, the agreement with Sandoz, if it takes effect, will grant an option to take an exclusive, worldwide license to make, use and sell medical products embodying technology discovered at Scripps. Scripps must disclose each new technology to Sandoz, and Sandoz must exercise its option to take a license within a certain defined

period of time. If Sandoz timely exercises its option, it must use reasonable efforts and due diligence to develop the technology into a product and promptly thereafter market the product.

If Sandoz declines to exercise its option to take a license or fails to meet its commercial development obligation with respect to a particular product, Scripps can license the technology to another party.

This is the same basic structure used in the current agreements Scripps has with J&J and PPG. The NIH is aware that Scripps and others have used that structure to maximize the benefits available to the public under the Bayh-Dole Act. Therefore, in setting up the arrangement with Sandoz having the same structure, Scripps did not consult with the NIH, but rather Scripps relied on existing statutes, regulations and written policy objectives to govern its behavior.

Scripps' Agreement with Sandoz Complies with the Letter and Spirit of the Bayh-Dole Act

To assure that the results of Scripps' research activities are brought to practical application for the public benefit, Sandoz is required to "use reasonable efforts and due diligence to develop" any technology or patent rights it licenses from Scripps "into commercially viable" products, "as promptly as is reasonably feasible, and thereafter market such developed" licensed products. In addition, each time Sandoz licenses a

technology from Scripps, the license agreement must contain a "research and development plan in reasonable detail setting forth steps Sandoz and, if applicable, Scripps intend to undertake in the forthcoming year," and Sandoz must provide to Scripps "an annual written report updating the research and development plan."

Finally, in its agreement with Scripps, Sandoz expressly

"acknowledges that its rights and obligations pursuant to this Agreement with respect to Scripps Technology and Scripps Patent Rights, and to Scripps' rights to Jointly Developed Technology, as applicable, may be subject to Scripps' obligations to, and the rights of, the United States Government, if any, which arise or result from Scripps' receipt of research support from the United State Government." This provision, together with a "severability" provision that takes effect in the event "any term or other provision of this Agreement is invalid, illegal, or incapable of being enforced by any Law or public policy . . . , " reflects the parties acknowledgement of the fact that federal law will take precedence over any inconsistent contractual obligations that may be contained in the agreement. These two provisions should allay any concerns that Scripps and Sandoz have attempted to enter into a contract that is contrary to federal law or the spirit of the Act.

It should be noted that all of Scripps' corporate sponsors have acknowledged that the federal government can attach new terms and conditions to its grant awards to institutions like Scripps, and that any rights Scripps conveys to a third party are subject to the right of the government to make such changes.

The Sandoz Agreement Does Not Impinge Academic Freedom at Scripps

The maintenance of academic freedom is critical to Scripps and its faculty. The NIH grant award process involves peer review of published research results. Most scientific journals require, as a condition for publication, that the scientist-author commit to sharing materials described in a publication with other academic scientists for purposes of confirming or extending the published research results. Therefore Scripps cannot and would not jeopardize the academic freedom of its scientists.

Under its agreement with Sandoz, Scripps retains the right to pursue research goals which Scripps, in its sole discretion, determines are worthy of pursuit. In addition, Scripps retains the "right to publish (whether orally, in writing or otherwise) results of its research in accordance with Scripps' policies which encourage publication of all research conducted at Scripps." Finally, Scripps retains the right to use any research results it produces for its "own educational and research purposes and the educational and research purposes of any other non-profit organization or any university, without Scripps or any

other non-profit organization or university being obligated to pay Sandoz any royalties or other compensation related thereto." That right includes the ability of Scripps to "continue its customary practices of transferring materials," such as recombinant DNA, cell lines, new compounds, and the like to other non-profit organizations and universities for educational and research purposes.

Ethical Standards at Scripps

Scripps employees are required to maintain high standards of ethical conduct in their relationships with grant agencies and industry. Each Scripps employee is required to (1) reject any arrangement involving unlawful or unethical conduct, (2) be under no influence which may cause him/her to serve his/her own or someone else's interests rather than that of Scripps, (3) avoid any arrangement, investment, employment relationship or interest which is or appears to be contrary to or in conflict with the best interest of Scripps or in any way may impair the employee's performance of duties or the exercise of independent judgment, (4) maintain security of confidential or privileged information relating to Scripps activities, and (5) inform his/her supervisor of any incident or potential situation concerning unethical behavior or conduct, conflict of interest or lack of information security.

Scripps employees must have all consulting arrangements reviewed by the Scripps Office of Technology Transfer for

potential conflicts of interest. Presently, one junior faculty member has a consulting agreement with Sandoz. Twenty-five faculty members, twelve of whom are senior, have or have had consultancies with J&J.

Scripps has never had any private consulting or vendor agreements with any members of its Board of Trustees, officers or employees.

Summary

Scripps performs basic biomedical research. It does not have the expertise and resources to translate the fruits of its research into commercial products. However, Scripps has effectively used the mechanisms set out in the Bayh-Dole Act to make important new therapies available to the public. The Bayh-Dole Act has provided Scripps with access to significant sources of non-governmental funding for its research programs. The corporate relationships at Scripps fostered by the Bayh-Dole Act are managed so as to preserve academic freedom and ethical standards.

CURRICULUM VITAE

ERNEST BEUTLER, M.D.

Work Address: Scripps Clinic and Research Foundation
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La Jolla, California 92037
(619) 554-8040

Home Address: 2707 Costebelle Drive
La Jolla, California 92037
(619) 457-5790

Date of Birth: September 30, 1928

Place of Birth: Berlin, Germany

Citizenship: United States

Marital Status: Married

Children: Four

Education: University of Chicago - Ph.B., with honors, 1946
University of Chicago - B.S., with honors, 1948
University of Chicago - M.D., with honors, 1950

Board Certification:

1958 - American Board of Internal Medicine.
1976 - Subspecialty Certification in Hematology.

Brief Chronology of Employment:

1950-1951 **Rotating Intern**, University of Chicago, Chicago, IL.
1951-1953 **Assistant Resident in Medicine**, University of Chicago Clinics, Chicago, IL.
1953-1955 **1st Lieutenant and Captain**, U.S. Army Medical Corps.
1955-1956 **Resident and Instructor in Medicine**, University of Chicago, Chicago, IL.
1956-1959 **Assistant Professor of Medicine**, University of Chicago, Chicago, IL.
1959-1978 **Chairman**, Division of Medicine and Director, Department of Hematology, City of Hope Medical Center, Duarte, CA.
1978-1982 **Chairman**, Department of Clinical Research, Scripps Clinic and Research Foundation, La Jolla, CA.
1978-1987 **Head**, Division of Hematology/Oncology, Scripps Clinic and Research Foundation, La Jolla, CA.
1982-Present **Chairman**, Department of Molecular and Experimental Medicine, Scripps Clinic and Research Foundation, La Jolla, CA.

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Other Academic Appointments:

1960-1964	Associate Clinical Professor of Medicine, University of Southern California, Los Angeles, CA.
1964-1965	Clinical Professor of Medicine, University of Southern California, Los Angeles, CA.
1965-1967	Clinical Professor of Medicine, University of California (CCM), Los Angeles, CA.
1967-1978	Clinical Professor of Medicine, University of Southern California, Los Angeles, CA.
1980-	Clinical Professor of Medicine, University of California, San Diego, CA.

Honorary Societies:

Phi Beta Kappa, 1948.
 Alpha Omega Alpha, 1950.
 American Academy of Arts and Sciences, 1975.
 National Academy of Sciences, 1976.
 National Academy of Clinical Biochemistry, 1991.

Societies:

American Federation for Clinical Research, 1955-1976.
 International Society of Hematology, 1956-
 Central Society for Clinical Research, 1956-
 American Society of Hematology, 1959-
 Executive Committee 1970-1973.
 Vice-President 1977.
 President 1979.
 American Society for Clinical Investigation, 1959-
 American Institute of Nutrition, 1960-
 American College of Physicians (Fellow), 1962-
 Western Society for Clinical Research, 1962-
 Corresponding Member, European Society of Hematology, 1964-
 Western Association of Physicians, 1965-
 President 1989.
 American Society of Human Genetics, 1965-
 Executive Committee 1968-1971.
 Association of American Physicians, 1969-

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Awards:

Salute to Medical Progress Award, Chicago, 1966.
 Distinguished Alumni Award, University of Chicago School of Medicine, 1973.
 Gairdner Foundation Award, 1975.
 James Blundell Prize, British Blood Transfusion Society, 1985.
 National Heart, Lung and Blood Institute MERIT Award, 1987.
 Mayo Soley Award of the Western Society for Clinical Investigation, 1992.
 Fifth Annual Award for Excellence in Clinical Research,
 General Clinical Research Centers Program, National Institutes of Health, 1993.

Special Lectures and Visiting Professorships:

Alice Messinger Band Memorial Lecture, University of Maryland, School of Medicine, Baltimore, MD, March 1966.
 Bruce K. Wiseman Memorial Lecture, Ohio State University, Columbus, OH, May 1969.
 Cleve Ewell Memorial Lecture, 74th Convention and Scientific Assembly, National Medical Association, San Francisco, CA, August 1969.
 Henry Stratton Lecture, American Society of Hematology, Atlanta, GA, December 1974.
 Paul M. Aggeler Lecture, San Francisco, CA, October 1976.
 Rufus Cole Lecture Rockefeller University, New York, NY, March 1977.
 Unger Memorial Lecture, Mt. Sinai Hospital, Cleveland, OH, October 1977.
 Mary H. Edens Medical Genetics Lectureship, University of Texas Medical Branch, Galveston, Texas, December 1977.
 John and Oral Sebelin Lecture, University of Iowa, May 1978.
 Gifford-Hill Visiting Professor, University of Texas, June 1979.
 Austin S. Weisberger Visiting Professor of Medicine, Case Western University, November 1980.
 Redlich Lectureship in Hematology, Cedars-Sinai Medical Center, January 1981.
 13th Annual Alice Sneed Visiting Professor, St. Joseph's Hospital, Houston, March 24 and 25, 1982.
 G. Izak Memorial Lecture, Hadassah University, Israel, March 1984.
 Clement A. Finch, Visiting Professorship, University of Washington, March 1985.
 James Blundell Award Lecture, Oxford, September 1985.
 Greenwalt Lectureship, Cincinnati, Ohio, September 1989.
 W.N. Valentine Lectureship in Hematology, University of California, Los Angeles, December 1989.
 Eastman Kodak Lectureship in Clinical Biochemistry, San Francisco, July 1990.
 First Annual E. Donnell Thomas Lecture, Fred Hutchinson Cancer Research Center, Seattle, July 1991.
 Spinoza Chair, University of Amsterdam, The Netherlands, November 1991.
 William C. Moloney Lecture, Brigham and Women's Hospital, Harvard Medical School, Boston, Massachusetts, November 20, 1992.

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Editorial Boards:

Blood, 1958-1964; 1967-1982; Associate Editor, 1978-1982.
 Journal of Pediatric Ophthalmology, 1964-1967.
 American Journal of Clinical Nutrition, 1964-1969.
 Excerpta Medica, 1966-
 Series Haematologica, 1966-1967.
 Haematologia Hungarica, 1966-
 Annals of Internal Medicine, 1975-1978.
 LAB, 1975-1977.
 Blood Cells, 1977-
 American Journal of Human Genetics, 1976-1979.
 Clinical and Laboratory Haematology, 1979-
 Associate Editor, Annual Review of Nutrition, 1983-1989
 Hematologic Pathology, 1987-
 Acta Haematologica 1988-

Consultantships:

Member, Scientific Advisory Council, Hyland Laboratories, 1964-1969.
 Chairman, Scientific Advisory Panel to the Trattner Foundation, 1964-1966.
 Member, Study Group on Blood Dyscrasias, American Medical Association, 1956-1965.
 Consultant, Committee on Iron Deficiency Anemia of the Council on Foods and Nutrition of the AMA, 1965.
 Member, Ad Hoc Committee on Iron Metabolism, Department of Drugs, A.M.A., 1965-1967.
 Member of World Health Organization Scientific Group on Haemoglobinopathies and Allied Disorders, Geneva, December 1965.
 Member of World Health Organization Scientific Group on The Standardization of Procedures for the Study of Glucose-6-Phosphate Dehydrogenase, Geneva, December 1966.
 Member of Board and Hemopoietic System Research Evaluation Committee, Veterans Administration, 1970-1971.
 Member of Hematology Study Section, NIH, 1970-1974.
 Member of Committee of Revision U.S. Pharmacopeia, 1970-1974.
 Consultant, Ad Hoc Committee on Adenine Specification, National Research Council of the National Academy of Sciences, 1971.
 Member, Board of Directors, International Committee for Standardization in Haematology, 1972.
 President, 1979-1980.
 Member, Ad Hoc Committee on Sickle Cell Disease, National Research Council, 1972.
 Member, Advisory Committee on Sickle Cell Anemia, Department of Public Health, State of California, 1972-1974.
 Member, Medical Advisory Committee Red Cross Blood Program, 1972-1978.
 Member, Research Review Committee for the American National Red Cross Blood Program, 1973-1977.

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Curriculum Vitae

- Member, Hemoglobinopathy Task Force, Center for Disease Control, Atlanta, Georgia, 1973-1974.
- Consultant, Veterans Administration Cooperative Study on the Sickle Cell Trait, 1973-1975.
- Member, Ad Hoc Committee on Current Status of Red Blood Cell Preservation National Research Council of the National Academy of Sciences, 1973.
- Consultant, Fenwal Laboratories, Morton Grove, Illinois, 1973-
- Member, Special Committee on Hemoglobin Standards, National Research Council of the National Academy of Sciences, 1973.
- Chairman, Scientific Advisory Committee of the Puget Sound Blood Center, Seattle, Washington, 1975-1981.
- Member, Cystic Fibrosis Foundation Scientific Advisory Council, 1976-1978.
- Member, International Scientific Advisory Committee to the Israeli Magen David Adom Central Bank and Fractionation Center, Israel, 1976.
- Broad-Based Genetic Disease Advisory Committee, State of California, 1977-
- Member, Blood Diseases and Resources Advisory Committee of the National Heart, Lung and Blood Institute, 1977-1982.
- Chairman, Task Force on Inborn Errors of Metabolism/NIH, Evaluation of Research Needs in Endocrinology and Metabolic Diseases, 1978-1979.
- Member, National Research Council, Committee on Space Biology and Medicine, 1979-1980.
- Member, Scientific Board of Visitors of the Oklahoma Research Foundation, 1980-1984.
- Member, National Committee for Clinical Laboratory Standards, Subcommittee on Cellular Enzymology, 1983-
- Blood Products Advisory Committee, FDA, 1984-1987.
- Member, Hematology Study Section, NIH, 1989-1990.
- Chairman, Sickle Cell Disease Task Force for the National Heart, Lung and Blood Institute, 1990.
- Member, PRP, Inc., Clinical Transfusion Committee, 1990-
- Member, Baxter Healthcare Scientific Advisory Board, 1991-

ARTICLES

1. Beutler E, Gezon HM: The effect of total body x-irradiation on the susceptibility of mice to influenza A virus infection. *J Immunol* 68:227-242, 1952.
2. Beutler E, Bergenstal DM: Perforated duodenal ulcer with neutropenia and death in a patient receiving phenylbutazone therapy. *Gastroenterology* 25:72-74, 1953.
3. Beutler E: Blood transfusion (minor note). *JAMA* 155:620, 1954.
4. Arnold J, Alving AS, Hockwald RS, Clayman CB, Dern RJ, Beutler E: Natural history of Korean vivax malaria after deliberate inoculation of human volunteers. *J Lab Clin Med* 44:723-726, 1954.
5. Arnold J, Alving AS, Hockwald RS, Clayman CB, Dern RJ, Beutler E, Jeffery GM: The effect of continuous and intermittent primaquine therapy on the relapse rate of Chesson strain vivax malaria. *J Lab Clin Med* 44:429-438, 1954.
6. Beutler E, Dern RJ, Alving AS: The hemolytic effect of primaquine. IV. The relationship of cell age to hemolysis. *J Lab Clin Med* 44:439-442, 1954.
7. Beutler E, Dern RJ, Alving AS: The hemolytic effect of primaquine. III. A study of primaquine-sensitive erythrocytes. *J Lab Clin Med* 44:177-184, 1954.
8. Dern RJ, Beutler E, Alving AS: The hemolytic effect of primaquine. II. The natural course of the hemolytic anemia and the mechanism of its self-limited character. *J Lab Clin Med* 44:171-175, 1954.
9. Beutler E: The development of acute myelogenous leukemia in a patient with reticulum cell lymphoma. *Ann Intern Med* 40:1217-1222, 1954.
10. Beutler E, Drennan W, Block M: The bone marrow and liver in iron deficiency anemia: A histopathologic study of sections with special reference to the stainable iron content. *J Lab Clin Med* 43:427-439, 1954.
11. Beutler E, Robson MJ, Jacobson LO: Prolongation of the lag phase of irradiated *Escherichia coli*. *Proc Soc Exp Biol Med* 85:682-685, 1954.
12. Beutler E, Dern RJ, Alving AS: The hemolytic effect of primaquine. VI. An in vitro test for sensitivity of erythrocytes to primaquine. *J Lab Clin Med* 45:40-50, 1955.
13. Weinstein IM, Beutler E: The use of Cr-51 and Fe-59 in a combined procedure to study erythrocyte production and destruction in normal human subjects and in patients with hemolytic or aplastic anemia. *J Lab Clin Med* 45:616-622, 1955.
14. Beutler E, Dern RJ, Flanagan CL, Alving AS: The hemolytic effect of primaquine. VII. Biochemical studies of drug-sensitive erythrocytes. *J Lab Clin Med* 45:286-295, 1955.

15. Alving AS, Arnold J, Hockwald RS, Clayman CB, Dern RJ, Beutler E, Flanagan CL: Potentiation of the curative action of primaquine in vivax malaria by quinine and chloroquine. *J Lab Clin Med* 46:301-306,1955.
16. Beutler E, Dern RJ: Previously unidentified transmissible agent in human blood. Experimental and clinical studies. *JAMA* 159:989-994,1955.
17. Arnold J, Alving AS, Hockwald RS, Clayman CB, Dern RJ, Beutler E, Flanagan CL, Jeffrey GM: The antimalarial action of primaquine against the blood and tissue stages of falciparum malaria (Panama, P-F-6 strain). *J Lab Clin Med* 46:391-397,1955.
18. Beutler E, Dern RJ, Flanagan CL: Effect of sickle-cell trait on resistance to malaria. *Br Med J* 1:1189-1192,1955.
19. Dern RJ, Beutler E, Arnold J, Lorincz A, Block M, Alving AS: Toxicity studies of pyrimethamine (Daraprim). *Am J Trop Med Hyg* 4:217-220,1955.
20. Dern RJ, Beutler E, Alving AS: The hemolytic effect of primaquine. V. Primaquine sensitivity as a manifestation of a multiple drug sensitivity. *J Lab Clin Med* 45:40-50,1955.
21. Beutler E: Iron enzymes in iron deficiency. I. Cytochrome C. *Am J Med Sci* 234:517-527,1957.
22. Beutler E: The clinical evaluation of iron stores. *N Engl J Med* 256:692-697,1957.
23. Beutler E, Robeson M, Bittenwieser E: The mechanism of glutathione destruction and protection in drug-sensitive and non-sensitive erythrocytes. In vitro studies. *J Clin Invest* 36:617-628,1957.
24. Beutler E: The glutathione instability of drug-sensitive red cells. A new method for the in vitro detection of drug-sensitivity. *J Lab Clin Med* 49:84-94,1957.
25. Blaisdell RK, Priest RE, Beutler E: Paroxysmal nocturnal hemoglobinuria: A case report with a negative Ham presumptive test associated with serum properdin deficiency. *Blood* 13:1074-1084,1958.
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27. Beutler E: Iron content of haemoglobin in iron deficiency. *Nature* 181:837-838,1958.
28. Beutler E, Blaisdell RK: Iron enzymes in iron deficiency. II. Catalase in human erythrocytes. *J Clin Invest* 37:833-835,1958.
29. Beutler E: Pre-operative management of blood loss anemia. *Surg Gynecol Obstet* 106:734-738,1958.

30. Beutler E, Robson M, Bittenwieser E: A comparison of the serum iron, iron-binding capacity, sternal marrow iron and other methods in the clinical evaluation of iron stores. *Ann Intern Med* 48:60-82, 1958.
31. Beutler E: The utilization of saccharated iron-59 oxide in red cell formation. *J Lab Clin Med* 51:415-419, 1958.
32. Beutler E: Iron enzymes in iron deficiency. *Ill Med J* 116:16-19, 1959.
33. Beutler E: Iron enzymes in iron deficiency. VI. Aconitase activity and citrate metabolism. *J Clin Invest* 38:1605-1616, 1959.
34. Dahl J, Blaisdell RK, Beutler E: Gastric ulceration in rats with experimentally-induced polycythemia. *Proc Soc Exp Biol Med* 101:622-624, 1959.
35. Beutler E, Yeh M: Aconitase in human blood. *J Lab Clin Med* 54:456-460, 1959.
36. Beutler E, Yeh M: Simplified method for the determination of citric acid. *J Lab Clin Med* 54:125-131, 1959.
37. Beutler E: Iron enzymes in iron deficiency. IV. Cytochrome oxidase. *Acta Haematol* 21:371-377, 1959.
38. Necheles T, Beutler E: The effect of triiodothyronine on the oxidative metabolism of erythrocytes. I. Cellular studies. *J Clin Invest* 38:788-797, 1959.
39. Beutler E, Yeh MKY, Necheles T: Incidence of the erythrocytic defect associated with drug sensitivity among Oriental subjects. *Nature* 183:684-685, 1959.
40. Beutler E: The red cell indices in the diagnosis of iron-deficiency anemia. *Ann Intern Med* 50:313-322, 1959.
41. Beutler E: The hemolytic effect of primaquine and related compounds. A review. *Blood* 14:103-139, 1959.
42. Beutler E: Congenital metabolic abnormalities of the erythrocyte: drug sensitivity and galactosemia. *Proc 4th Int Cong Clin Chem* 110-118, Edinburgh:1960.
43. Beutler E: Introductory speech. Symposium on hereditary blood diseases. *Proc 8th Int Cong Hematol* pp. 1098-1100, Tokyo, Sept. 4-10:1960.
44. Beutler E: Sensitivity to drug-induced hemolytic anemia. A hereditary metabolic disorder of the erythrocyte. *Proc 8th Int Cong Hematol* pp. 1101-1106 Tokyo, Sept. 4-10:1960.
45. Beutler E: Iron enzymes in iron deficiency. *Blut* 6:130-133, 1960.
46. Beutler E, Lareh S, Tanzi F: Iron enzymes in iron deficiency: VII. Oxygen consumption measurements in iron-deficient subjects. *Am J Med Sci* 239:759-765, 1960.

47. Beutler E, Larsh SE, Gurney CW: Iron therapy in chronically fatigued, non-anemic women: A double-blind study. *Ann Intern Med* 52:378-394, 1960.
48. Beutler E, Bittenwieser E: The regulation of iron absorption. I. A search for humoral factors. *J Lab Clin Med* 55:274-280, 1960.
49. Beutler E, Hofstra D: Autocannibalism: The etiology of nerve-resection anemia. *Blood* 15:370-375, 1960.
50. Beutler E, Blaisdell RK: Iron enzymes in iron deficiency. V. Succinic dehydrogenase in rat liver, kidney and heart. *Blood* 15:30-35, 1960.
51. Beutler E: Sensitivity to hemolytic drugs: An inborn error of red blood cell metabolism. *Am J Clin Nutr* 9:700-704, 1961.
52. Beutler E, Mikus BJ: The effect of sodium nitrite and paraaminopropiophenone on blood methemoglobin levels and red blood cell survival. *Blood* 18:455-467, 1961.
53. Beutler E: The effect of methemoglobin formation in sickle cell disease. *J Clin Invest* 40:1856-1871, 1961.
54. Trujillo J, Fairbanks VF, Ohno S, Beutler E: Chromosomal constitution in glucose-6-phosphate-dehydrogenase deficiency. *Lancet* 2:1454-1455, 1961.
55. Beutler E: Hematology: Iron metabolism. *Annu Rev Med* 12:195-210, 1961.
56. Beutler E, Baluda MC, Kelly BM: The role of methemoglobin in the mechanism of drug-induced hemolytic anemia. *Proc 9th Cong Int Soc Hematol* pp. 233-244 Mexico City:1962.
57. Beutler E, Fairbanks VF: The normal human female as a mosaic of X-chromosome activity: Studies using glucose-6-phosphate dehydrogenase as a genetic marker. *Proc 9th Cong Int Soc Hematol* pp. 43-53 Mexico City:1962.
58. Beutler E: Drug-induced haemolytic anaemias and the mechanism and significance of Heinz body formation in red blood cells. *Nature* 196:1095-1096, 1962.
59. Beutler E: A look to the future: Hematology. *World-Wide Abstracts* 5:10-11, 1962.
60. Necheles T, Spratt J, Ford E, Beutler E: Effect of thyroid hormone on the pathways of glucose oxidation in the intact rat. *Proc Soc Exp Biol Med* 109:114-115, 1962.
61. Beutler E, Kelly BM, Beutler F: The regulation of iron absorption. II. Relationship between iron dosage and iron absorption. *Am J Clin Nutr* 11:559-567, 1962.
62. Fairbanks VF, Beutler E: A simple method for detection of erythrocyte glucose-6-phosphate dehydrogenase deficiency (G-6-PD spot test). *Blood* 20:591-601, 1962.

63. Beutler E, Larsh SE: Relative effectiveness of ferroglycine sulfate and ferrous sulfate. *N Engl J Med* 267:538-540,1962.
64. Beutler E, Baluda MC: The role of methemoglobin in oxidative degradation of hemoglobin. *Acta Haematol* 27:321-333,1962.
65. Beutler E, Yeh M, Fairbanks VF: The normal human female as a mosaic of X-chromosome activity: Studies using the gene for G-6-PD deficiency as a marker. *Proc Natl Acad Sci USA* 48:9-16,1962.
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68. Beutler E, Yeh MKY: Erythrocyte glutathione reductase. *Blood* 21:573-585,1963.
69. Beutler E, Duron O, Kelly BM: Improved method for the determination of blood glutathione. *J Lab Clin Med* 61:882-890,1963.
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71. Beutler E: Autosomal inactivation. *Lancet* 1:1242-1243,1963.
72. Beutler E: Hematology. *Med World News* page 176:1964.
73. Beutler E, Baluda M, Donnell GN: A new method for the detection of galactosemia and its carrier state. *J Lab Clin Med* 64:694-705,1964.
74. Beutler E, Sparkes RS: Variation of glucose-6-phosphate dehydrogenase in different populations. *Lancet* 2:95,1964.
75. Beutler E, Ohno S, Goldenburg EW, Yettra M: Chromosome-21 and paroxysmal nocturnal hemoglobinuria. *Blood* 24:160-163,1964.
76. Beutler E: Drug-induced blood dyscrasias. III. Hemolytic anemia. *JAMA* 189:143-144,1964.
77. Beutler E, Baluda MC: Simplified determination of blood adenosine triphosphate using the firefly system. *Blood* 23:688-689,1964.
78. Beutler E, Baluda MC: The separation of glucose-6-phosphate dehydrogenase-deficient erythrocytes from the blood of heterozygotes for glucose-6-phosphate dehydrogenase deficiency. *Lancet* 1:189-192,1964.
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83. Beutler E: Genetically determined errors of metabolism of the red cell. Scand J Haematol 10:23-33,1965.
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85. Beutler E, Collins Z: Methaemoglobin reduction: Studies using galactose as substrate. Scand J Haematol 2:343-354,1965.
86. Beutler E: Advances in the study of red cell enzyme defects. Nouv Rev Fr Hematol 5:793-806,1965.
87. Beutler E, Collins Z: Hybridization of glucose-6-phosphate dehydrogenase from rat and human erythrocytes. Science 150:1306-1307,1965.
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91. Beutler E, Day RW, Baluda M, Polk K: Screening for galactosemia among mentally retarded patients. J Ment Defic Res 9:61-68,1965.
92. Beutler E: Drug-induced blood dyscrasias. III. Hemolytic anemia. J Oral Ther Pharmacol 1:567-568,1965.
93. Beutler E: Glucose-6-phosphate dehydrogenase deficiency and non-spherocytic congenital hemolytic anemia. Semin Hematol 2:91-138,1965.
94. Beutler E, Mathai C: Role of haemoglobin in the protection of reduced glutathione against destruction by "oxidant drugs". Nature 205:1121-1122,1965.
95. Beutler E, Duron O: Effect of pH on preservation of red cell ATP. Transfusion 5:17-24,1965.
96. Beutler E, Baluda MC: The separation of glucose-6-phosphate dehydrogenase deficient erythrocytes from blood of heterozygotes for glucose-6-phosphate dehydrogenase deficiency. Folia Haematol (Leipz) 83:410-415,1965.
97. Beutler E, Duron O: Factors influencing the preservation of red cell ATP on storage. Folia Haematol (Leipz) 83:403-409,1965.
98. Krill AE, Beutler E: Red-light thresholds in heterozygote carriers of protanopia: Genetic implications. Science 149:186-188,1965.

99. Beutler E, Baluda MC, Sturgeon P, Day R: A new genetic abnormality resulting in galactose-1-phosphate uridyltransferase deficiency. *Lancet* 1:353-354, 1965.
100. Beutler E: Cellular mosaicism and heterogeneity in red cell disorders. *Am J Med* 41:724-733, 1966.
101. Beutler E, Collins Z: Hybridization studies in the further characterization of erythrocyte glucose-6-phosphate dehydrogenase. *Experientia* 22:827-828, 1966.
102. Masters H, Solomon J, Bateman JR, Bernstein H, Beutler E: Bovine bile derivative treatment for cancer. A critical evaluation. *Calif Med* 105:440-441, 1966.
103. Mathai CK, Beutler E: Electrophoretic variation of galactose-1-phosphate uridyl transferase. *Science* 154:1179-1180, 1966.
104. Mathai CK, Pilson MEQ, Beutler E: Galactose metabolism in the sea lion. *Proc Soc Exp Biol Med* 123:603-604, 1966.
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CHAPTERS

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 **SANDOZ**

TIMOTHY G. ROTHWELL
PRESIDENT AND CHIEF EXECUTIVE OFFICER

TEL 201 503 8125
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March 5, 1993

Hand-Delivered

The Honorable Ron Wyden
Chairman
House Subcommittee on Regulation,
Business Opportunities and Technology
B-363 Rayburn House Office Building
Washington, DC 20515-6318

*Sandoz/AILSWORTH
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Dear Chairman Wyden:

Thank you for your letter dated February 25, 1993, relating to the Subcommittee's "inquiry into business relationships between independent, tax-exempt medical research institutes which may receive a significant degree of federal grant support, and private companies intent on commercializing drug or device discoveries from those institutions."

Since I will be out of the country during the Subcommittee's March 11 hearing, I will be unable to be present. We are pleased to answer the specific questions set forth in your letter.

1. Please describe the elements of the agreement between Scripps and Sandoz, with particular regard to exclusivity in the transfer of technologies from Scripps to Sandoz, and the value Scripps will receive in return for those technology rights.

As discussed with Messrs. Jennings and Forrer of your staff yesterday, we understand that TSRI will submit our option and proposal for a research agreement to NIH, a decision which I support. Accordingly, it is expected that you and your staff will have access to those documents within the very near future. Our proposed arrangement speaks for itself. We only would note that, if we exercise our option to enter into a research agreement, it will not take effect for several years, at least.

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We are proud of our anticipated collaboration with TSRI. We request that the proprietary terms of the proposal be kept confidential (their release can only benefit our competitors). We confidently stand by the terms of our relationship. For those reasons, we feel that it was in the best interest of the future of America's biomedical research community -- the preeminent, worldwide leader in this field -- that the TSRI documents were submitted to NIH. In that way, they can be openly examined in an informed manner, without being subject to mischaracterization or oversimplification.

Finally, we wish to address your question regarding the purported "value" of this agreement. It is impossible for Sandoz Pharmaceuticals to quantify the "value," that TSRI might receive. The "value" to Sandoz Pharmaceuticals is in the opportunity to collaborate with a leading biomedical research institution with the possibility -- at some undefined future point -- of providing tangible benefits of measurable practical value to the American consumer by commercializing technologies developed under the agreement.

2. To what extent did Sandoz confer or consult with NIH prior to the signing of this agreement?

In accordance with existing laws, policies, and practices pertaining to this issue, we did not consider it necessary or even appropriate to consult with NIH prior to the signing of our option agreement.

- a. Do you believe that such consultations are appropriate in light of the significant degree of support Scripps receives from the federal government, and the likelihood that federal grants will support at least some technologies of interest to Sandoz?

This question would be most appropriately answered by Federal grantees and other recipients of Federal funding.

We simply note that, during our review of the governing laws both before, during, and after our negotiations with TSRI, we did not find even the suggestion -- much less the mandate -- that grantees and/or their private collaborating partners should consult with NIH or other agencies before entering private biomedical research agreements such as the one which Sandoz Pharmaceuticals entered with TSRI.

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- b. In your view, what rights does NIH have to demand information regarding the Sandoz agreement?

We are not aware of any law, regulation, or policy which grants NIH any consulting or related authority with respect to this or similar agreements. Unquestionably, NIH and other Federal agencies possess statutorily-mandated audit authority. Sandoz Pharmaceuticals will leave evaluations of whether or not that audit authority was appropriately exercised in the TSRI-NIH matter to those who regularly make such judgments. More importantly, our own legal analysis of that audit authority leads us to conclude that its breadth, in fact, may be unclear in some respects. That determination must be made, in the first instance, by agency personnel who seek to exercise the authority.

3. Given the scope and breadth of federal support of Scripps' research, does NIH play any role in the development of pricing of drugs which may be commercialized from that activity?

Based upon Sandoz Pharmaceuticals' review of the governing laws and policies, there is no role that current law grants to NIH in the pricing of products developed as a result of our private biomedical research agreement with TSRI.

- a. If not, is it your belief that the federal government should play some consultive role in the pricing of drugs or devices which may result from technologies developed at the institute?

Issues of whether current policy on this subject is suitable to the task or should be modified to give NIH a role are more suitably answered by Federal grantees and others who receive Federal funding. On an individual corporate basis, Sandoz Pharmaceuticals would simply note that the inclusion of any third party -- governmental or private -- in proprietary pricing decisions could create a significant disincentive to the willingness of private industry to engage in collaborative biomedical research.

4. Please describe the degree of cooperation you have extended to the NIH in its inquiries regarding the arrangement with Scripps.

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Sandoz Pharmaceuticals has not received any communication from NIH relating to our agreement with TSRI. We stand willing to cooperate with the NIH in any appropriate manner, upon request.

5. Scripps receives a significant level of federal funding. Would this level of funding likely continue even during the term of the ten-year, exclusive agreement with Sandoz?

Sandoz Pharmaceuticals has no basis upon which to comment on the possibility that TSRI may continue receiving Federal grants or other Federal funding. This question would appear to be addressed most appropriately to NIH and any other Federal agencies that are providing funding to TSRI.

- a. If yes, isn't it apparent that this drug company is receiving a significant taxpayer financed subsidy without offering the government any opportunity to (1) approve the agreement with the institute, or (2) confer on the pricing of drugs or devices which may result?

Sandoz Pharmaceuticals is not in a position to comment on the likelihood that Federal funding will continue flowing to TSRI. Consequently, we are unable to respond to this question.

6. I have suggested that unless or until the government has the opportunity to play a meaningful role (see question #4), NIH funding to these private research institutions ought to be withheld. Please comment on this proposal.

We are not aware of any existing legal authority for withholding funds on this basis. However, we feel such a practice would have a chilling effect on the important concept of CRADA research.

- a. Are there other ways for the government to exercise some control, and demonstrably protect the public interest and investment, in situations like the Scripps-Sandoz arrangement?

We recognize that there are many policy options in this area that might eventually be adopted by Congress. We will comply with the letter and the spirit of any new policies that are adopted. At this time, however, we are not in a position to comment one way or the other on such options.

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7. This subcommittee also is concerned about the public interest so far as it is involved in the development of technology transfer arrangements between private drug or device manufacturers whose owners may also be officers, directors or key personnel in private, non-profit and tax-exempt research institutions. There is some concern by this member, and apparently by other members, that the tax-exempt status of the institutions may be used in a way not envisioned by Congress in these arrangements. In particular, access by government subsidized technologies may be awarded non-competitively, and to corporate "insiders." Do you share this concern?

We have no position at this time. We have not had the opportunity to examine this issue and are accordingly unable to offer any constructive comments to the Subcommittee.

- a. If yes, what procedural, regulatory, or legislative changes would you suggest to close loopholes or end abuses?

Sandoz Pharmaceuticals has no position on those issues at this time.

8. Does Sandoz, either in its contract with Scripps or in individual agreements with individuals at the institution, currently have private consulting arrangements or other kinds of personal services contracts with (1) officers of Scripps, (2) members of the Scripps board of directors, or (3) other key Scripps personnel such as senior scientists, project researchers or department heads?
- a. If yes, please describe the scope of those contracts or agreements including the names and titles of Scripps personnel involved, their remuneration from Sandoz and the type of work those persons will do for the drug company.
- b. If these arrangements exist, please provide the dates contracts were signed, and the date when they were to become effective.

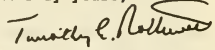
Sandoz Pharmaceuticals does not, to the best of my knowledge, have any such agreements. I understand that our Swiss affiliate has one agreement with a TSRI scientist which provides for remuneration for specific services on a daily fee basis.

The Honorable Ron Wyden
March 5, 1993
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CONFIDENTIAL

We appreciate having this opportunity to provide the
above answers to the Subcommittee.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Timothy G. Rothwell". The signature is fluid and cursive, with a large, stylized "R" at the end.

Timothy G. Rothwell



JOHN P. HALL, JR.
VICE PRESIDENT
FEDERAL RELATIONS
CORPORATE STAFF

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March 10, 1993

Mr. Steven C. Jennings
Staff Director
Committee on Small Business
Subcommittee on Regulation, Business
Opportunities and Energy
Room B-363 Rayburn House Office Building
Washington, D.C. 20515

Dear Mr. Jennings:

In response to your letter dated February 26, 1993 we wish to provide you with the following answers to your questions.

1. Q. Please describe the elements of the agreement between Scripps and J&J, with particular regard to exclusivity in the transfer of technologies from Scripps to J&J, and the value Scripps will, or has received in return for those technology rights.
 - A. Our understanding is that Scripps provided NIH with our general funding agreement on 3/8/93. The agreement is several hundred pages and difficult to summarize in a paragraph. Additionally, we understand that Scripps has disclosed to the NIH the existence of our other funding agreements with Scripps.
2. Q. To what extent did J&J confer or consult with NIH prior to the signing of this agreement?

Do you believe that such consultations are appropriate in light of the significant degree of support Scripps receives from the federal government, and the likelihood that federal grants will support at least some technologies of interest to J&J?

In your view, what rights does NIH have to demand information regarding the J&J agreement?

- A. We did not consult with NIH prior to signing our 1981 and 1987 Agreements with Scripps, and we are not aware of any obligation to do so. We are not aware of any

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rights the NIH has to demand information from J&J. In any event we intend to cooperate with such requests.

3. Q. Given the scope and breadth of federal support of Scripps' research, does NIH play any role in the development of pricing of drugs which may be commercialized from that activity?

If not, is it your belief that the federal government should play some consultive role in the pricing of drugs or devices which may result from technologies developed at the institute?

- A. NIH has played no role in pricing drugs from Scripps activity. After more than 11 years of providing major funding to Scripps, J&J had the first drug approved on February 26, 1993 for a very small patient population.

We do not believe that NIH should play a consultive role in pricing.

Additionally, it is our opinion if NIH or any other governmental agency is a determining factor in setting prices of new products that may have originally been researched by academia, it could devastate one of the most entrepreneurial, high-tech, competitive industries; that being biotechnology. As most of these companies are started with ideas from academic institutions, the venture capital companies will not want to provide the seed money to start-up companies who operate in a price controlled environment. One can already see the reaction from the investment community to biotech stocks due to comments made by government officials.

4. Q. Please describe the degree of cooperation you have extended to the NIH in its inquiries regarding the arrangement with Scripps.
- A. We have asked Scripps to fully cooperate with NIH since we have not been contacted directly by NIH.
5. Q. To your knowledge, what return if any has the NIH, the federal government more generally, or the taxpayer, received from the exclusive arrangement between Scripps and J&J?
- A. The NIH, the federal government and taxpayers have benefitted from enhanced funding of NIH-funded projects, resulting in advancements of basic research.

(Also, see answer to #3.)

6. Q. I have suggested that unless or until the government has the opportunity to play a meaningful role (see question #4), NIH funding to these private research institutions ought to be withheld.

Please comment on this proposal.

- A. We do not think it is appropriate for us to comment on this issue.

6. (cont.)

- Q. Are there other ways for the government to exercise some control, and demonstrably protect the public interest and investment, in situations like the Scripps-Sandoz, or Scripps-J&J arrangements?

- A. We believe that the public is well-served by the private and public sectors working together in basic research which leads to practical applications of the technology. These public/private collaborations benefit the American public.

Additionally, collaborations, such as the one we have with Scripps, can benefit the global competitiveness of the U.S. healthcare industry.

- Q. This subcommittee also is concerned about the public interest so far as it is involved in the development of technology transfer arrangements between private drug or device manufacturers whose owners may also be officers, directors or key personnel in private, non-profit and tax-exempt research institutions.

There is some concern by this member, and apparently by other members, that the tax-exempt status of the institutions may be used in a way not envisioned by Congress in these arrangements. In particular, access to government subsidized technologies may be awarded non-competitively, and to corporate "insiders."

Do you share this concern?

If yes, what procedural, regulatory or legislative changes would you suggest to close loopholes or end abuses?

- A. We would hope that the ethics of the people involved would preclude any problems of conflict of interest. However, most institutions are set up to work with private industry and are capable of balancing these interests.

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7. Q. Does J&J, either in its contract with Scripps or in individual agreements with individuals at the institution, currently have private consulting arrangements or other kinds of personal services contracts with (1) officers of Scripps, (2) members of the Scripps board of directors, or (3) other key Scripps personnel such as senior scientists, project researchers or department heads?

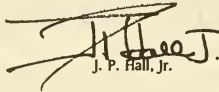
If yes, please describe the scope of those contracts or agreements including the names and titles of Scripps personnel involved, their remuneration from J&J and the type of work those persons have done for the drug company.

If these arrangements exist, please provide the dates contracts were signed, and the dates when they were to become effective.

- A. We have consulting agreements with academic personnel at Scripps. A list of these agreements is attached.

Please let me know if I may be of further assistance.

Sincerely,



J. P. Hall, Jr.

Attachment

ATTACHMENT1993 SCRIPPS CONSULTING AGREEMENTS

<u>PERSON</u>	<u>FIELD OF STUDY</u>	<u>TERM OF AGREEMENT</u>	<u>CONTRACTED AMOUNT (\$000)</u>
Lerner	Immuno*	Thru 1994	60 (Per Year)
Dixon	Immuno	Annual	30
Burton	Immuno	Annual	12.5
Barbas	Immuno	Annual	12
Wilson	Immuno	Annual	5
Ulevitch	Infect**	Annual	18
Tobias	Infect	Annual	8
Mathison	Infect	Annual	2
Glenn	Infect	Annual	8
Grimshaw	Infect	Annual	10
McMillan	Diagnostic	Semi-annual	2.5
Curtiss	Diagnostic	Semi-annual	5
Nakamura	Diagnostic	Semi-annual	12.5

*Immuno = Immunology

**Infect = Infectious Disease

3/9/93

SANDOZ PHARMACEUTICALS CORPORATION
59 ROUTE 10, EAST HANOVER, NEW JERSEY 07936-1080



FOR FURTHER INFORMATION CONTACT:

Craig Burrell, M.D.
(202) 223-6263

**STATEMENT
SUBMITTED FOR THE RECORD
OF THE HEARING HELD BY
THE HOUSE SUBCOMMITTEE ON
REGULATION, BUSINESS OPPORTUNITIES, AND TECHNOLOGY
BY
SANDOZ PHARMACEUTICALS CORPORATION**

March 11, 1993

SANDOZ PHARMACEUTICALS CORPORATION IS PLEASED TO SUPPLEMENT THE RECORD OF THE HEARING WHICH THE SUBCOMMITTEE HAS CONVENED THIS MORNING CONCERNING COLLABORATIVE BIOMEDICAL RESEARCH AGREEMENTS BETWEEN PRIVATE INDUSTRY AND PRIVATE RESEARCH INSTITUTIONS.

WE ARE SUBMITTING THIS STATEMENT SINCE TIMOTHY ROTHWELL, PRESIDENT AND CHIEF EXECUTIVE OFFICER OF SANDOZ PHARMACEUTICALS CORPORATION, WAS UNABLE TO APPEAR BECAUSE HE HAD PREVIOUS COMMITMENTS WHICH PREVIOUSLY WERE COMMUNICATED TO THE CHAIRMAN.

THERE HAVE BEEN CERTAIN CRITICISMS OF THE PROPOSED COLLABORATION BETWEEN THE SCRIPPS RESEARCH INSTITUTE AND SANDOZ PHARMACEUTICALS BECAUSE SANDOZ IS A FOREIGN COMPANY. AT THE OUTSET, WE WANT TO DISPEL THE NOTION THAT BEING FOREIGN IS BAD.

WHILE OUR PARENT COMPANY IS A SWISS COMPANY, THE SANDOZ PRESENCE IN THE UNITED STATES IS, INDEED, DECIDEDLY AMERICAN. SINCE 1919, WHEN SANDOZ CHEMICAL WORKS WAS INCORPORATED IN THE STATE OF NEW YORK, WE HAVE MADE A SUBSTANTIAL AND EVER-INCREASING IMPACT UPON THE AMERICAN ECONOMY.

THE U.S. SANDOZ COMPANIES NOW EMPLOY ABOUT 12,000 PEOPLE IN THIS COUNTRY, AND SANDOZ EMPLOYEES WILL BE FOUND IN EVERY ONE OF THE 50 STATES. SUBSTANTIAL SANDOZ FACILITIES ARE LOCATED IN 11 STATES. ALL OF THE BUSINESS ENTITIES ARE AMERICAN COMPANIES, AND THE VAST MAJORITY OF OUR EMPLOYEES AND TOP EXECUTIVES IN THIS COUNTRY ARE AMERICANS. NOT ONLY DO WE PAY SUBSTANTIAL CORPORATE TAXES, BUT OUR U.S. PAYROLL RESULTS IN ADDITIONAL TAXES TO THE FEDERAL AND STATE GOVERNMENTS OF WELL OVER \$100,000,000.

BECAUSE OF OUR COMMITMENT TO THE U.S. ECONOMY AND THE COMMUNITIES IN WHICH WE OPERATE, WE FIND ANY SUGGESTIONS THAT WE ARE "BUYING" AMERICAN TECHNOLOGY PARTICULARLY DISTURBING. WHILE AT HARVARD, LABOR SECRETARY ROBERT REICH JOINED MANY LEADING ECONOMISTS IN MAKING A PERSUASIVE CASE THAT THE LOCATION OF A CORPORATION'S HEADQUARTERS IS FAR LESS IMPORTANT THAN ITS COMMITMENT TO CREATING AND MAINTAINING HIGH-WAGE, HIGH-SKILL JOBS IN THE UNITED STATES. IN "WHO IS US?," REICH ARGUES THAT, "OWNERSHIP OF THE CORPORATION IS PROFOUNDLY LESS RELEVANT TO AMERICA'S ECONOMIC FUTURE THAN THE SKILLS, TRAINING, AND KNOWLEDGE COMMANDED BY AMERICAN WORKERS -- WORKERS WHO ARE INCREASINGLY EMPLOYED WITHIN THE UNITED STATES BY FOREIGN-OWNED CORPORATIONS." SANDOZ PHARMACEUTICAL'S CORPORATE NATIONALITY IS LESS IMPORTANT THAN THE BENEFITS WE PROVIDE OUR EMPLOYEES, OUR CUSTOMERS, AND OUR ECONOMY. IN PRESIDENT CLINTON'S OWN WORDS (AS STATED IN HIS INAUGURAL ADDRESS), "THERE IS NO LONGER A CLEAR

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DIVISION BETWEEN WHAT IS FOREIGN AND WHAT IS DOMESTIC." IN SUM, SCIENCE KNOWS NO BOUNDARIES.

SANDOZ PHARMACEUTICALS STANDS READY TO COOPERATE WITH THE SUBCOMMITTEE IN ITS CONSIDERATION OF THE PUBLIC POLICY ISSUES UNDERLYING BIOMEDICAL RESEARCH AGREEMENTS SUCH AS THE OPTION AND PROPOSAL FOR A RESEARCH AGREEMENT BETWEEN SANDOZ AND SCRIPPS. WE TRUST THAT THE SUBCOMMITTEE WILL CONDUCT A COMPREHENSIVE REVIEW OF ALL SUCH AGREEMENTS, AND WE LOOK FORWARD TO TESTIFYING BEFORE THE SUBCOMMITTEE IN THAT CONTEXT.

HOWEVER, THE SUBCOMMITTEE WILL NOT EXAMINE THOSE BROADER ISSUES TODAY, SINCE NIH HAS NOT YET POSSIBLY HAD TIME TO ANALYZE ALL SUCH AGREEMENTS. THEREFORE, ANY MESSAGE FLOWING FROM THIS MORNING'S HEARING IS LIKELY TO BE A FRAGMENTED ONE. FRANKLY, IT IS UNCLEAR TO US WHY THE SUBCOMMITTEE HAS FOCUSED ON THE BIOMEDICAL RESEARCH AGREEMENT THAT HAS BEEN PROPOSED BETWEEN OUR COMPANY AND SCRIPPS. ITS DECISION TO DO SO IS PARTICULARLY CONFUSING TO US SINCE NOT ONLY IS ITS VALIDITY UNDER EXISTING LAWS UNQUESTIONED, BUT IT IS ALSO TOTALLY CONSISTENT WITH THE POLICY OBJECTIVES CONGRESS SOUGHT TO ACHIEVE IN THE BAYH-DOLE ACT. (THOSE POLICY OBJECTIVES ARE DESCRIBED IN THE APPENDED MATERIALS). NONETHELESS, SANDOZ PHARMACEUTICALS WILL TAKE THIS OPPORTUNITY TO BRIEFLY PROVIDE SOME GENERAL CONTEXT TO THE PROPOSED AGREEMENT AND TO DESCRIBE THE IMPLICATIONS OF SUCH COLLABORATIVE EFFORTS FOR SANDOZ PHARMACEUTICALS AND THE BIOMEDICAL RESEARCH COMMUNITY IN GENERAL.

A PROPOSED AGREEMENT WITH SCRIPPS WAS DISCUSSED BECAUSE SANDOZ PHARMACEUTICALS RECOGNIZED THE INTRINSIC SCIENTIFIC VALUE OF COLLABORATING WITH A LEADING BIOMEDICAL RESEARCH INSTITUTION SUCH AS SCRIPPS. IF THE OPTION IS EVENTUALLY EXERCISED, WE WOULD ANTICIPATE THE POTENTIAL FOR PROVIDING TANGIBLE BENEFITS TO THE AMERICAN CONSUMER. EVEN IF THAT POTENTIAL WERE NOT REALIZED, THE KNOWLEDGE THAT MIGHT BE GAINED AS A RESULT OF THE AGREEMENT WOULD CONTRIBUTE SIGNIFICANTLY TO THE ADVANCEMENT OF SCIENCE AND HEALTH CARE. CONSEQUENTLY, THE AMERICAN TAXPAYERS' INVESTMENT IN SCRIPPS -- THROUGH GRANTS AND OTHER FEDERAL FUNDING -- WOULD BE SIGNIFICANTLY AUGMENTED, AS SCRIPPS WOULD CONDUCT PIVOTAL BIOMEDICAL RESEARCH WHICH IT COULD NOT OTHERWISE AFFORD.

THERE IS NO DOUBT, WHATSOEVER, THAT COOPERATION BETWEEN PRIVATE INDUSTRY AND NIH IS INVALUABLE TO OUR SOCIETY. A RECENT ARTICLE PUBLISHED BY DR. STEVEN M. PAUL, THE FORMER SCIENTIFIC DIRECTOR OF THE NATIONAL INSTITUTE OF MENTAL HEALTH, A DIVISION OF NIH, APTLY STATED: "BUT BIOMEDICAL RESEARCH IS IN THE MIDST OF A REVOLUTION THAT IS TRANSFORMING OUR BASIC UNDERSTANDING OF DISEASE AND OUR ABILITY TO DIAGNOSE AND TREAT PREVIOUSLY HOPELESS CONDITIONS. . . . THE GOVERNMENT CANNOT PRODUCE THESE NEW MEDICINES. OUR CONTRIBUTIONS ARE VALUABLE, BUT OUR PROGRAMS DO BASIC, RELATIVELY NONTARGETED RESEARCH. WE SIMPLY DO NOT HAVE THE MONEY, PERSONNEL, OR ORGANIZATION NEEDED TO DEVELOP SPECIFIC DRUGS AND TAKE THE HIGH RISKS OF BRINGING THEM TO MARKET."

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IT IS PRECISELY THAT PHILOSOPHY, AS SET FORTH SO ELOQUENTLY BY DR. PAUL, THAT HAS MOTIVATED SANDOZ PHARMACEUTICALS TO CONSIDER SUCH AGREEMENTS. WE AGREE WITH DR. PAUL THAT NO GOVERNMENT CAN AFFORD TO FUND, DIRECTLY OR INDIRECTLY, THE BIOMEDICAL RESEARCH NECESSARY TO PROVIDE CONSUMERS AROUND THE WORLD WITH THE BEST POSSIBLE HEALTH CARE.

INFORMAL AND FORMAL AGREEMENTS OF THIS NATURE -- WITH ACADEMIA -- HAVE HELPED US TO ADVANCE SIGNIFICANTLY THE HEALTH CARE AVAILABLE TO THE AMERICAN PUBLIC. DURING THE PAST SEVERAL YEARS ALONE, SANDOZ PHARMACEUTICALS HAS INTRODUCED FOUR DRUGS CLASSIFIED AS 1-A (A 1-A DRUG IS AN IMPORTANT NEW THERAPEUTIC ENTITY -- IN OTHER WORDS, A BREAKTHROUGH) BY THE FOOD AND DRUG ADMINISTRATION. SUCH INNOVATIVE PHARMACEUTICAL PRODUCTS ARE A REFLECTION OF SANDOZ PHARMACEUTICALS' INTENSE R&D COMMITMENT. MORE IMPORTANTLY, THEY WOULD NOT HAVE BEEN POSSIBLE WITHOUT THE TIRELESS EFFORTS OF OUR EMPLOYEES IN THE UNITED STATES. THROUGH OUR INCREASING DEDICATION TO ACHIEVING OUR SCIENTIFIC OBJECTIVES -- AND IN CONJUNCTION WITH THE MANY INSTITUTIONS WITH WHOM WE CONDUCT COLLABORATIVE BIOMEDICAL RESEARCH -- SANDOZ PHARMACEUTICALS HOPES TO CONTINUE MAKING POSITIVE CONTRIBUTIONS TO THE HEALTH OF AMERICANS FOR MANY YEARS TO COME.

IN CONCLUSION, SANDOZ PHARMACEUTICALS IS CONFIDENT THAT, WHEN THE PENDING INQUIRIES ARE COMPLETED, ALL PARTIES WILL CONCLUDE THAT OUR PROPOSED BIOMEDICAL RESEARCH AGREEMENT WITH SCRIPPS IS PROPER IN EVERY RESPECT.

PATENT REEXAMINATION

HEARING BEFORE THE COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

NINETY-SIXTH CONGRESS

FIRST SESSION

ON

S. 1679

A BILL TO AMEND THE PATENT LAWS. TITLE 35 OF THE
UNITED STATES CODE

NOVEMBER 30, 1979

Serial No. 96-43

Printed for the use of the Committee on the Judiciary



U.S. GOVERNMENT PRINTING OFFICE

WASHINGTON 1980

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the kind of people who make it possible for them to do an outstanding job.

We have not yet gotten to the point where we trust the national defense to the private sector. There are other jobs that the Government can do well. Mr. Chairman, Senator Schmitt, I think that the President's bill embodies the best of S. 414, embodies the best of S. 1215, and provides the additional extension for utilization in areas that neither of those bills attempt. I would hope that we can join together in supporting the President's proposal.

Thank you, Mr. Chairman.

[The statement and materials referred to follow:]

STATEMENT OF JORDAN J. BARUCH, ASSISTANT SECRETARY FOR SCIENCE AND TECHNOLOGY, U.S. DEPARTMENT OF COMMERCE

Mr. Chairman, members of the Committees, I appreciate this opportunity to appear before you today to discuss government patent policy—the allocation of rights in patentable inventions made in the course of federally sponsored or supported research and development. Government patent policy bears a major responsibility for the pace of industrial innovation in America and for the ability of the Federal agencies to attract the most qualified contractors to participate in their research and development work. In addition, government patent policy provides us with an opportunity to further the special role in our society played by small businesses and nonprofit organizations.

THE INDUSTRIAL INNOVATION PROCESS

President Carter, in his Industrial Innovation Message to the Congress of October 31, 1979, emphasized that:

"Industrial innovation—the development and commercialization of new products and processes—is an essential element of a strong and growing American economy. It helps ensure economic vitality, improved productivity, international competitiveness, job creation, and an improved quality of life for every American. Further, industrial innovation is necessary if we are to solve some of the Nation's most pressing problems—reducing inflation, providing new energy supplies and better conserving existing supplies, ensuring adequate food for the world's population, protecting the environment and our natural resources, and improving health care.

Industrial innovation is primarily the responsibility of the private sector. In our economic system, the management of every firm must decide whether to innovate. Innovation is possible either by developing and marketing new products or by finding and employing new ways of making existing products. Since new products offer opportunities for increased sales, and since new processes can offer cost savings, the profit motive provides a powerful stimulus to innovative activity by the private sector.

While it is the private decision-maker who determines whether innovation takes place, the Federal government can establish a climate which either encourages or discourages innovative activity. Federal actions affect innovation within the firm to the degree that they affect the ability of the firm to innovate or the decision calculus of its executives.

The importance of patent rights

The progress of an invention from idea to commercial product or process ordinarily is long and expensive. The temporary patent monopoly provided for by the Constitution encourages an entrepreneur to invest risk capital to develop an invention secure in the knowledge that, if his efforts are successful, he will have the opportunity to obtain a return on his investment before his competitors are able to copy cheaply what he produced with such difficulty.

Patent rights affect positively the entrepreneur's ability to raise risk capital. Patent rights offer the successful inventor-entrepreneur a respite from competition in which to enjoy the fruits of success.

Patent rights are particularly important to small firms. Firms which already possess competitive advantages such as a popular trade name, manufacturing experience, established channels of distribution, or size, are more likely to obtain exclusive commercial rights to attract risk capital and recover commercialization costs than firms which do enjoy such advantages. Given our present concerns, this is an important point.

The record of small innovative firms

While the record of large innovative firms is substantial, the record of small businesses based on technological innovation—especially those in high technology areas—is even more impressive. A 1975 study commissioned by the National Science Foundation reported that in the period from 1953 to 1973 about one-half of the major innovations produced by United States industry were made by firms with fewer than one thousand employees and about one-quarter were made by firms with fewer than 100 employees.

Many of you are familiar with the study of the Department of Commerce Technical Advisory Board which showed that in the years from 1969 to 1974, a group of large innovative firms experienced sales growth of 13.2 percent while a similar group of mature firms had 11.4 percent sales growth. Despite the similarity of their growth in sales, employment in the mature firms grew by only 0.6 percent while employment in the innovative firms grew by 4.3 percent—over seven times as much.

In this same period, a group of young, high technology businesses enjoyed a sales growth of 42.5 percent—roughly three times as great as their larger counterparts. Their employment in that period grew by 40.7 percent—almost ten times the rate of the large innovative firms, and some 65 times as much as the large mature firms.

Turning to the actual numbers for the period studied, six large mature firms having combined sales of 36 billion dollars created twenty-five thousand new jobs. At the same time, five young high technology firms with one-fortieth their sales—\$75 million dollars—created thirty-five thousand new jobs. Five large innovative firms with sales of 21 billion dollars created 106 thousand new jobs.

This evidence runs contrary to the conventional wisdom which holds that innovation, especially when applied to the production process, throws people out of work. In fact, over time innovations that improve the productivity of an industry commonly increase the number of workers employed within the industry.

GOVERNMENT PATENT POLICY

The Federal government provides about one-half of all the money spent each year in this country on research and development. The allocation of rights in patentable inventions made during the course of that work affects the pace of industrial innovation in the Nation through its effect on firms' incentives and ability to innovate. This allocation affects the willingness of firms to undertake government research and development work because they must weigh the benefits of the government dollar against the impact on their commercial business of diverting resources to do government work.

As President Carter observed in his Industrial Innovation Message:

"For over thirty years the Federal agencies supporting research and development in industry and universities have had conflicting policies governing the disposition of [patent] rights resulting from that work. This confusion has seriously inhibited the use of those patents in industry."

There has been much debate on what Administration policy should be. There has been wide support, however, for nine propositions about a desirable government patent policy. Government patent policy should strive to:

- (1) Obtain the best contractor effort for the government;
- (2) Maximize technological innovation;
- (3) Promote competition within the private sector;
- (4) Recognize the public's equity in the products of federally sponsored or supported research and development;
- (5) Strengthen the research programs of universities; and
- (6) Provide special incentives for small businesses; and should:
- (7) Be uniform, in the sense that like cases should be treated alike no matter which government agency provides the support and in the sense that there should be only a single set of patent regulations with which potential government contractors must deal;
- (8) Be flexible, in the sense that differing cases should be treated appropriately, that is, not necessarily identically; and
- (9) Be as clear and as simple as possible.

The source of the confusion noted by the President has been the inability, until now, of any Administration to resolve the diverse considerations involved into a single policy. The historical development of existing government patent policies is described briefly in the statement of purpose and need for the Administration's draft Government Patent Policy Act of 1980. At this point, I request that the official draft of the bill, with its accompanying statement of purpose and need and section-by-section analysis, be included in the record. The bill formally will be transmitted to the Congress next week.

This bill implements the President's announcement in his Industrial Innovation Message of support for uniform government patent policy legislation. Participants in the policy debate which preceded the drafting of the Administration bill have argued that the government should implement some form of either a "contractor title" or a "government title" policy. Under a contractor title policy, the contractor would receive title in any invention resulting from federally sponsored or supported research and development, and the government would receive a nonexclusive license to practice the invention. Under the government title policy, the government would receive title in any invention, and the contractor would receive a nonexclusive license to practice the invention.

Proponents of each policy have presented several distinct reasons in favor of their viewpoints. Those in favor of a government title policy argue that the primary purpose of the patent laws is to create an incentive for businesses to engage in research and development activities. A patent provides its owner with the right to foreclose competition for a limited period in the marketing of the covered invention; consequently, if the patent holder is able to commercialize the patented invention, it may be able to recover not only its original research and development costs but also to achieve an advantage over its competitors who are unable to use the invention.

Government sponsorship of research and development, however, generally eliminates some of the risk associated with such activities. The contractor's incentive to perform the work is provided by the payment it receives under the government contract, not by the mere possibility that it may be able to exploit a patented invention at some future time. To provide the contractor with title in the invention, it is claimed, would unjustly enrich the contractor at the expense of the public, which has paid for the research and development from which the invention was made.

Government title supporters further argue that government ownership of inventions will ensure the widest possible availability to the public of the technological knowledge embodied therein. Moreover, contractors do not necessarily need to receive title in federally-financed inventions to induce them to commercialize the resulting inventions. They receive other competitive benefits through their participation in government contracts, such as the opportunity to train key personnel, expand their research facilities, develop know-how, and obtain access to government technology. These benefits could provide any necessary competitive advantage to induce the contractor to commercialize the invention. Even if some form of exclusive rights in the invention is necessary to induce its commercialization, the government contractor is not necessarily the firm most capable of achieving the desired result. Rather, any need for exclusivity could be satisfied by issuing exclusive licenses after the invention has been identified.

Finally, it has been argued that contractor ownership of inventions may tend to enhance the recipient's market power and therefore may contribute to the concentration of economic power in a limited number of corporations.¹

Advocates of contractor title point out that government ownership with the offer of unrestricted public use has resulted in an exceptionally low rate of commercial application of federal-owned inventions. The costs and risks of commercializing an invention, developing it and its market, often are so substantial that commercialization will not take place or even be attempted in the absence of exclusive commercial rights. Ironically, the free public right to use a federally-owned patent thus results, in practical terms, in a denial of the opportunity to use the invention.

Contractor title proponents also assert that a government title policy discourages the most qualified firms from participating in government research and development projects. These firms often have invested heavily in research and development related to the government project; consequently, their experience and technological advancement would enable them to perform the government contract more inexpensively.

¹ There is little evidence, however, that patent policy has had any impact on market structure. A 1968 study by Harbridge House, Inc., probably the most extensive study of government patent policy ever done, indicates that most contractors have been willing to license patents obtained from government research, thereby enabling new or small firms to establish a position in the market. Further, a 1977 study by Utterback and Murray, of the M.I.T. Center for Policy Alternatives, revealed that government procurement of innovative products from small firms was a much more important influence on industry development than government patent policy.

Even if there were evidence indicating that research under a contractor-rights policy increases the market power of large firms, this more effectively could be considered in the selection of contractors. By adopting this strategy, competition would be improved not just through the allocation of patent rights but also through the allocation of contract funds, where most of the competitive impact appears to occur. Moreover, explicit "march-in" rights to address instances where demonstrable anticompetitive effects result from the granting of exclusive commercial rights are a final assurance that a properly designed policy of giving contractors exclusive commercial rights need have no significant anticompetitive potential.

sively and more effectively than could other potential contractors. These firms refuse to bid on the government work, however, because the cost to them of publicly disclosing their independently acquired information in conjunction with the disclosure of an invention made under the government contract would be much greater than the profits they could expect to receive under the contract.²

Another problem with the policy of government ownership is that it provides little incentive for contractors to disclose their inventions to the government. Rather, the contractor either may maintain the invention's secrecy or make an incomplete disclosure and subsequently attempt to seek its own patent of the federally-financed technology. The incentive for nondisclosure is especially great for those contractors that would be required to divulge independently-acquired information when they revealed a federally-financed invention to the government. A contractor title policy would ameliorate the disclosure disincentive by eliminating the financial penalty associated with disclosure. Further, a contractor title policy would create an incentive to disclose by providing contractors with property rights in federally-financed inventions on the condition that such inventions are reported to the government.

The conflicting arguments of the government title and contractor title proponents lead to one conclusion: neither policy, alone, provides the most beneficial means for allocating rights to federally sponsored or supported inventions. Although a contractor title policy may induce both an increased participation in government research and development projects and a higher commercialization rate of federally-financed inventions, such a policy would be unnecessary to induce participation or commercialization in many instances. Under a government title policy, many qualified contractors nevertheless would participate in the government contracting process and some federally-financed inventions would be commercialized. In such situations, implementation of a contractor title policy could be necessary and possibly might conflict with the public interest. Strict adherence to a government title policy, on the other hand, would prevent not only the most qualified contractors from participating in certain government research and development projects but also the commercialization of certain inventions.

One possible resolution would be a general government title policy under which the agencies possessed liberal authority to induce the participation of the most competent contractors by waiving government rights in the invention at the time of

² To some, the degree to which Government patent policy encourages or discourages contractor participation in Government research and development programs is the single most important consideration. Advocates of one and another policy have disagreed over the extent to which the ancillary benefits from government sponsorship and support assure adequate participation. These benefits include the Government dollar itself, the know-how developed by the firm, and the attendant advantage over other firms in competition for follow-up development and procurement by the Government. There is very little empirical evidence on the effect of government patent policy on firm participation in the contracting process. The Harbridge House study contains case studies in which firms refused to undertake Government contracts under a Government title, no rights to the contractor, policy. However, the study gives no indication of the significance of the problem beyond stating that the policy choice is most important where the prospective contractors is engaged in similar research for a commercial business in which patent protection is important.

This seems a reasonable conclusion. Presumably, the Government only sponsors or supports research that is not being pursued adequately by the private sector on its own. This research represents projects for which the expected return without Government support is less than the research and development cost required for invention. If many firms are capable of performing the research, they compete by announcing the lowest payment for which they will undertake a particular project. Firms will have similar perceptions of expected benefits because any rights to inventions can be sold. Moreover, if firms value their inventive inputs at opportunity costs reflecting their productivity in related research, then estimates of cost will be very similar. That is, firms with skilled research staffs will require less of their more valuable time to complete a project than those with inferior personnel. Consequently, the breakeven payment for all firms will be approximately the same, and competition for the award will drive down the required Government funding to that level.

The only difference between policies which do or do not assure the contractor exclusive commercial rights is that the firm includes the value of the patent in its calculation of expected return when it operates under the more favorable policy. Without the prospect of exclusive commercial rights, firms will require a larger payment from the Government to breakeven. Under either policy, however, the Government should be able to offer most qualified firms adequate economic incentives to participate in the contracting process.

Contractor rights advocates argues, however, that a firm which has invested its own resources in the field of research will not participate under an unfavorable policy because proprietary information used in completing the contract must also be turned over to the Government. The value of that information includes monopoly profits from other inventions that the firm could market in the private sector. Therefore, the opportunity cost and breakeven payment for the contract will be higher for the advanced firms than for other firms. As a result, the advanced firm will choose in some cases not to participate in the contracting process.

contracting. In addition, the government could induce the commercialization of any invention in which it holds title by deciding to grant any necessary exclusive license after the invention had been identified. The administrative burdens created by this policy, however, make it impractical and undesirable. An agency would be required to allocate much of its resources to the negotiation with the contractor of the appropriate allocation of invention rights, a subject of only secondary importance to the agency when compared to the primary purpose of the contract. Moreover, each agency would be required to allocate vast resources to the evaluation and promotion of federally-owned inventions. If an agency failed to grant any necessary exclusive license, the penalty paid by the public would be the noncommercialization of the invention.

The President's patent policy would reduce the administrative burden and the uncertainty that accompany present policies. The proposal, which includes elements of both the government title policy and the contractor title policy, allocates patent rights in federally sponsored or supported inventions according to unambiguous, generally applicable rules. Contractors that are small businesses and nonprofit organizations will receive title in federally-financed inventions, but the government will retain title in inventions made by all other contractors. Ordinarily, the other contractors automatically will receive exclusive licenses in whatever particular fields of use in which they agree to commercialize the invention.

The receipt of title by small businesses and nonprofit organizations is intended to provide these contractors with an advantage over their larger competitors. The advantage is justified by the special place of these organizations in our society. It also is justified by the fact that, unlike larger contractors whose commercial interest in an invention is apt to be limited by the fields in which it already is, or is planning to become, engaged, small businesses and nonprofit organizations share a strong incentive to attempt to commercialize an invention to the widest possible extent.

The President's decision to provide contractors other than small businesses and nonprofit organizations with automatic exclusive licenses in particular fields of use recognizes that a complete transfer of title to the contractor usually is unnecessary to induce its participation in government research and development work and its commercialization of the invention. The government retains the right to license the invention or otherwise make it available to the public in all fields of use not selected by the contractor.

Although the contractor will know at the time of contracting that it automatically will be able to receive exclusive licenses under any forthcoming invention in particular fields of use, it will not actually receive those licenses until the invention has been identified, its intention to commercialize has been announced, and its selection of fields of use have been submitted to the contracting agency. After the contractor has submitted complete information regarding the invention, its intention to commercialize, and its selection of fields of use, the agency has ninety days in which it may determine whether the contractor's acquisition of an exclusive license in any selected field of use would be contrary to the requirements of the agency's mission, national security, or the antitrust laws. To reduce administrative burdens and to increase the security of the contractor's expectations of receiving exclusive commercial rights in the invention, the scope of the agency's possible inquiry underlying this determination is limited. An agency review will focus only on those unforeseen circumstances of which it has become aware since the time of contracting that now require it to deny the contractor exclusive commercial rights with respect to a particular field of use. The contractor will not be denied an exclusive license solely on the basis of facts that were known or reasonably foreseeable by the agency at the time of contracting. If such facts do exist at the time of contracting, an agency normally will deviate from the standard patent rights clause so that the contractor will know at that time that it will not receive an exclusive license to practice a forthcoming invention in a particular field of use.

The agency's ability to deviate from the standard patent rights clause and to terminate a contractor's title or exclusive rights in an invention provide it with additional flexibility to fulfill its mission and protect the public interest. Although these powers are intended to be exercised only in unusual circumstances, they are available to assist the agency in fulfilling its mission, protecting the public interest, and promoting the commercialization of contract inventions.

CONCLUSIONS

Enactment of this bill would stimulate the industrial innovation process by contributing to the more effective utilization of inventions made in the course of federally sponsored or supported research and development work. Further, the bill

would resolve longstanding policy issues, answers to which the Congress, the Executive Branch, industry, and the public actively have sought for a generation. The bill is designed to reduce the administrative burden now imposed upon contractors and Government agencies alike.

Further, the bill responds to the 1972 recommendations to the Congress of the bipartisan Commission on Government Procurement, that legislation be enacted which would make uniform the Federal practices in the area of allocating the rights to contract inventions and make clear the government's authority to grant exclusive licenses under federally-owned inventions. The bill also would codify the basic policy concepts of Executive Order 10096, the provisions of which uniformly would be applicable to all Federal employees.

It is anticipated that, following enactment and implementation of this bill, greater commercial use will be made of the technology resulting from the Federal government's research and development effort, in turn creating additional employment, a higher standard of living, and an overall economic benefit to the United States as a whole, while protecting the public against any possible wrongful contractor conduct.

PROPOSAL

A BILL

To establish a uniform Federal system for management, protection, and use of inventions that result from federally sponsored or supported research or development, and for related purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Government Patent Policy Act of 1980".

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TITLE I—POLICY

FINDINGS

Sec. 101. The Congress, recognizing the profound impact of science, engineering, and technology policy on the well-being, health, and safety of the Nation, finds that:

- (1) Inventions that result from federally sponsored or supported research and development constitute a valuable national resource;
- (2) Federal policy on allocation of patent rights in such inventions should stimulate innovation, should meet the needs of the Government, should foster competition, should recognize the equities of Government contractors and Federal employees-inventors, and should provide small businesses and educational institutions with special incentives to participate in Federal research and development programs and to commercialize resulting inventions; and
- (3) The public interest would be advanced if greater efforts were made to promote commercial use of new technology that results from federally sponsored or supported research and development.

PURPOSE

Sec. 102. The purposes of this Act are—

- (1) To establish an effective Federal system for management and use of inventions that result from federally sponsored or supported research and development;
- (2) To allocate patent rights in inventions that result from federally sponsored or supported research and development in ways that—
 - (A) Stimulate innovation,
 - (B) Encourage participation of all qualified contractors,
 - (C) Foster competition,
 - (D) Reduce administrative burdens on Federal agencies and their contractors,
 - (E) Promote widespread public use of inventions made with public support, and
 - (F) Provide special incentives to small businesses and educational institutions;
- (3) To allocate equitably patent rights in Federal employee inventions;
- (4) To provide for domestic and foreign patenting of federally owned inventions and licensing of federally-owned patent rights, with the objective of strengthening the Nation's economy and expanding its domestic and foreign markets; and
- (5) To amend or repeal inconsistent laws.

TITLE II—CONTRACT INVENTIONS

CONTRACT INVENTIONS—REPORTING

Sec. 201. (a) This Title applies to "contract inventions", which in this Act are inventions made in the course of or under Federal contracts.

(b) Every contractor will provide the responsible agency with timely written reports on each contract invention containing:

- (1) Complete technical information on the invention,
- (2) A list of each country, if any, in which the contractor elects to file a patent application on the invention, and
- (3) Unless the contractor is a small business or nonprofit organization, a list of each field of use in which the contractor intends to commercialize the invention, or otherwise achieve public use of the invention. Each field will be described with sufficient particularity to allow the Government to identify those fields of use not encompassed by the described field.

The Government neither will publish nor release these reports until the contractor or the Government has had a reasonable time to file patent applications or one year has passed since receipt of all the information required by subsection (b)(1) of this section, whichever is earlier, and may so withhold such information in other reports or records.

(c) If the responsible agency determines that the contractor has unreasonably failed to file reports as required by subsection (b) of this section, the contractor may be deprived of any or all of the rights it otherwise would have under this Title.

ALLOCATION OF RIGHTS—SMALL BUSINESSES AND NONPROFIT ORGANIZATIONS

Sec. 202. (a) A contractor that is a small business or a nonprofit organization shall acquire title to its contract invention in each country it lists under section 201(b)(2).

in which it files a patent application within a reasonable time. However, title will be subject to the Government's minimum rights under section 205 and march-in rights under section 206.

(b) The Government will have the right to acquire title to any patent on a contract invention in each country in which the contractor elects not to file a patent application or fails to file within a reasonable time.

ALLOCATION OF RIGHTS—OTHER CONTRACTORS

Sec. 203. (a) The Government will acquire title to all patents on any contract invention whenever the contractor is not a small business or nonprofit organization.

(b) If such a contractor files within a reasonable time a patent application on a reported contract invention in any country it lists under section 201(b)(2), it will receive an exclusive license under the patent in each described field of use, with the exclusive right to grant sublicenses. However, its license will be subject to the Government's minimum rights under section 205 and march-in rights under section 206.

(c) The contractor automatically will acquire by operation of law the right to receive an exclusive license, pursuant to subsection (b) of this section, ninety days after it provides the responsible agency with all of the information required to be disclosed by section 201(b), except that it will not acquire the right to receive an exclusive license in any field of use as to which the agency notifies the contractor within the ninety-day period that it has made a determination under subsection (d) of this section.

(d) The contractor will not acquire an exclusive license in any field of use if the responsible agency determines that the contractor's possession of such a license—

(1) Would be contrary to the requirements of the agency's mission;

(2) Would impair national security; or

(3) Would violate the antitrust laws if the receipt by the contractor of such a license were deemed an acquisition of another corporation.

(e) An agency determination under subsection (d) of this section will include written reasons for the determination. The contractor may appeal the determination to the United States Court of Claims within sixty days after the contractor has been notified of the determination. That Court will have exclusive jurisdiction to determine the matter de novo and to affirm, reverse, or modify the agency determination, specifically including authority to require that the contractor receive any exclusive license provided for by this section.

(f) If the responsible agency determines that the national interest would not be affected adversely, the agency may grant the contractor title to any contract invention in any foreign country in which the contractor agrees to file a patent application.

CONTRACTOR LICENSE

Sec. 204. Any contractor that complies with section 201(b) automatically will receive by operation of law nonexclusive, royalty-free licenses to practice the contract invention in all countries where it does not receive title under section 202 and in all fields of use and in all countries in which it does not receive an exclusive license under section 203. These nonexclusive licenses may be revoked only to the extent necessary to allow the Government to grant exclusive licenses under Title IV.

MINIMUM GOVERNMENT RIGHTS

Sec. 205. (a) The Government will have the following minimum rights in any contract invention:

(1) The right to require from the contractor written reports on the use of the invention,

(2) A royalty-free worldwide right or license to practice the invention or have it practiced for the Government, and

(3) The right to license or sublicense State, local, or foreign governments to practice the invention or have it practiced for them, if the agency determines at the time of contracting that acquisition of this right would serve the national interest.

(b) Whenever the Government has rights in any invention under this Title, each patent application and patent on the invention will include a statement that the invention was made with Government sponsorship or support and that the Government has rights in the patents.

MARCH-IN RIGHTS

Sec. 206. (a) In any field of use, the Government may wholly or partly terminate the contractor's title or exclusive rights in any patent on a contract invention: may require the contractor to grant appropriate licenses or sublicenses to responsible applicants; or, if necessary, may grant such licenses or sublicenses itself. The Government may take such actions only—

(1) If the contractor has not taken and is not expected to take timely and effective action to achieve practical application of the invention in one or more of the selected fields of use;

(2) If necessary to protect the national security;

(3) If necessary to meet requirements for public use specified by Federal regulation;

(4) If the contractor's rights in the invention violate the antitrust laws if the contractor's original receipt of those rights were deemed an acquisition of assets of another corporation; or

(5) If the contractor has failed to comply with the reporting requirements of this Act.

(b) These march-in rights may be exercised by the responsible agency on its own initiative or on a petition from an interested person justifying such action.

(c) Whenever under this section an agency requires a contractor to grant a license or sublicense, it may specify reasonable terms, including the royalties to be charged, if any; the duration of the license or sublicense; the scope of exclusivity; and the fields of use to be covered.

DEVIATION AND WAIVER

Sec. 207. (a) An agency may deviate from the allocation of patent rights in contract inventions provided for in any standard patent rights clause established under section 209 acquiring more or fewer rights in the inventions, to further the agency's mission and the public interest. It may so deviate on a class basis only in accordance with regulations issued either under section 209 or, unless prohibited by those regulations, by the agency. Case-by-case deviations may be authorized by the head of the agency or his designee, and described in the Federal Register.

(b) The national security and antitrust march-in rights reserved by sections 206(a)(2), 206(a)(4), and 206(c) may not be waived under any circumstances.

(c) Rights reserved by sections 203 and 206(a)(1) may be waived only:

(1) In contracts involving cosponsored, cost-sharing, or joint-venture research or development to which the contractor makes a substantial contribution of funds, facilities, technology, or equipment; or

(2) In contracts with a contractor whose participation is necessary for the successful accomplishment of the agency's mission but cannot be obtained under the standard patent rights clause.

TRANSFER OF RIGHTS TO CONTRACTOR EMPLOYEES

Sec. 208. The contractor's employee-inventor may receive some or all of the contractor's rights under this Title with the permission of the contractor and the approval of the responsible agency. The corresponding obligations of the contractor under this title then will become obligations of the employee-inventor.

REGULATIONS AND STANDARD PATENT RIGHTS CLAUSE

Sec. 209. The Office of Federal Procurement Policy will direct the issuance of regulations to implement this Title. The regulations will establish a standard patent rights clause or clauses, to be included in each Federal contract except as provided in section 207.

TITLE III—INVENTIONS OF FEDERAL EMPLOYEES

EMPLOYEE INVENTIONS

Sec. 301. This Title applies to "employee inventions", which in this Act are inventions made by Federal employees.

REPORTING OF INVENTIONS

Sec. 302. (a) Federal employees will file timely written reports on any invention they make. Such reports will be made to the employee's agency and will contain complete technical information concerning the invention. The Government neither will publish nor release a report until there has been a reasonable time to file

patent applications or until one year has passed since the final disposition of rights under this Title, whichever is earlier.

(b) If the responsible agency determines that the employee-inventor unreasonably has failed to file a report as required by subsection (a) of this section, the employee may be deprived of any or all of the rights he otherwise would have under the Title.

CRITERIA FOR ALLOCATION OF RIGHTS

Sec. 303. The responsible agency will determine the rights of the Government and of Federal employee-inventors in any inventions made by employee-inventors through the use of the following criteria:

(1) If the invention bears a direct relation to the duties of the employee-inventor or was made in consequence of his employment, the Government will acquire all rights in the invention.

(2) If the invention neither bears a direct relation to the duties of the employee-inventor or was made in consequence of his employment, but was made with a contribution from Federal funds, facilities, equipment, materials, or information not generally available to the public, or from services of other Federal employees on official duty, the employee-inventor will receive all rights in the invention, except as provided in paragraph (4) of this section. However, these rights will be subject to a nonexclusive, royalty-free, worldwide license to the Government to practice the invention or have it practiced for the Government.

(3) If the agency finds insufficient interest in an invention to justify exercising its rights under paragraph (1) of this section, it may permit the employee-inventor to receive any or all of those rights, subject to the Government's rights as described in paragraph (2) of this section. However, nothing in this paragraph will prevent the agency from publishing the invention or otherwise dedicating it to the public.

(4) If the agency determines that national security might be impaired if the employee-inventor were to receive rights in an invention under paragraph (2) or (3) of this section, the Government will acquire all rights in the invention.

(5) The Government will claim no rights under this Act in any employee-invention not covered by paragraphs (1) or (2) of this section.

(6) Notwithstanding paragraph (1) of this section, an agency may enter into agreements providing for appropriate allocation of rights in inventions that result from research or development to which other parties have substantially contributed.

PRESCRIPTIONS

Sec. 304. (a) There will be a rebuttable presumption that an employee invention falls within the criteria of section 303(1) if it was made by a Federal employee who is employed or assigned to—

(1) Invent, improve, or perfect any art, machine, manufacture, or composition of matter;

(2) Conduct or perform research or development work;

(3) Supervise, direct, coordinate, or review federally sponsored or supported research or development work; or

(4) Act as liaison among agencies or individuals engaged in the work specified in paragraphs (1), (2), or (3) of this subsection.

(b) There will be a rebuttable presumption that an invention falls within the criteria of section 303(2) if it was made by any other Federal employee.

REVIEW OF AGENCY DETERMINATIONS

Sec. 305. Agency determinations under sections 302 and 303 will be reviewed whenever—

(1) The agency determines not to acquire all rights in an invention, or

(2) An aggrieved employee-inventor requests a review. Standards and procedures for this review will be prescribed in the regulations issued under section 309.

REASSIGNMENT OF RIGHTS

Sec. 306. If an agency finds on the basis of new evidence that it has acquired rights in an invention greater than those to which the Government was entitled under the criteria of section 303, it will grant the employee-inventor such rights as may be necessary to correct the error.

INCENTIVE AWARDS PROGRAM

Sec. 307. (a) Agencies may monetarily reward and otherwise recognize employee-inventors as an incentive to promote employee inventions and the production and disclosure of employee inventions. For this purpose agencies may make awards under the Federal incentive awards system (5 U.S.C. Ch. 45, 10 U.S.C. Ch. 57, and implementing regulations), as modified by this section.

(b) The amount of an award for an invention will be based on—

- (1) The extent to which the invention advances the state of the art;
- (2) The scope of application of the invention;
- (3) The value of the invention to the Government or the public; and
- (4) The extent to which the invention has come into public use.

(c) Awards for an invention of up to \$10,000 may be made by the head of an agency.

(d) Awards of over \$10,000 but less than \$35,000 may be made by the head of an agency to—

- (1) Civilian employees, with the approval of the Office of Personnel Management;
- (2) Members of the Armed Forces, with the approval of the Secretary of Defense;
- (3) Members of the United States Coast Guard when not operating as a service in the Navy, with the approval of the Secretary of Transportation;
- (4) Members of the Commissioned Corps of the United States Public Health Service, with the approval of the Secretary of Health and Human Services; and
- (5) Members of the Commissioned Corps of the National Oceanic and Atmospheric Administration, with the approval of the Secretary of Commerce.

(e) Awards of more than \$35,000 may be made to employee-inventors by the President upon recommendation of the head of an agency.

(f) Acceptance of a cash award under this section constitutes an agreement that any Government use of an invention for which the award is made forms no basis for further claims against the Government by the recipient, his heirs, or his assigns.

(g) Any cash award or expense for honorary recognition of an employee-inventor will be paid from the fund or appropriation of the agency receiving the invention's primary benefit.

INCOME SHARING FROM PATENT LICENSES

Sec. 308. In addition to awards as provided in section 307, an agency may share income received from any patent license with the employee-inventor.

REGULATIONS

Sec. 309. (a) The Secretary of Commerce shall issue regulations to implement this Title.

(b) Any determination of an appointing official under subsection 208(b) of title 18, United States Code, that relates to promotion of an employee invention by the employee-inventor will be subject to regulations prescribed by the Secretary of Commerce with concurrence of the Office of Government Ethics and the Attorney General.

TITLE IV—LICENSING OF FEDERALLY-OWNED INVENTIONS

COVERED INVENTIONS

Sec. 401. This Title applies to the licensing of all federally-owned patent rights including licenses or sublicenses granted or required to be granted by the Government under section 206. However, it does not apply to licenses established by the other sections of Title II of this Act.

EXCLUSIVE OR PARTIALLY EXCLUSIVE LICENSES

Sec. 402. (a) An agency may grant exclusive or partially exclusive domestic licenses under federally-owned patent rights not automatically licensed under section 203 only if, after public notice and opportunity for filing written objections, it determines that—

(1) The desired practical application is not likely to be achieved under a nonexclusive license; and

(2) The scope of proposed exclusivity is not greater than reasonably necessary.

(b) An agency may grant exclusive or partially exclusive foreign licenses under federally-owned patent rights after public notice and opportunity for filing written objections and after determining whether the interests of the Government or the United States industry in foreign commerce will be enhanced.

(c) An agency will not grant any license under this section if it determines that such a grant would violate the antitrust laws if the licensee's receipt of such a license were deemed an acquisition of assets of another corporation.

(d) Agencies will maintain periodically updated records of determinations to grant exclusive or partially exclusive licenses. These records will be publicly available.

MINIMUM GOVERNMENT RIGHTS

Sec. 403. Each license granted under section 402 will contain such terms and conditions as the agency finds appropriate to protect the interests of the Government and the public, including provisions reserving to the Government:

(1) The right to require from the licensee written reports on the use of the invention,

(2) A royalty-free, worldwide right to practice the invention or have it practiced for the Government, and

(3) The right to license State, local, or foreign governments to practice the invention or have it practiced for them if the agency determines that reservation of this right would serve the national interest.

MARCH-IN RIGHTS

Sec. 404. (a) The Government will have the right to terminate any license granted under section 402 in whole or in part, but only—

(1) If the licensee has not taken and is not expected to take timely and effective action to achieve practical application of the invention in each of the fields of use affected;

(2) If necessary to protect national security;

(3) If necessary to meet requirements for public use specified by Federal regulation;

(4) If the licensee's rights in the invention violate the antitrust laws if the licensee's original receipt of those rights were deemed an acquisition of assets of another corporation; or

(5) If the licensee has failed to comply with the terms of the license.

(b) These march-in rights may be exercised by the responsible agency on its own initiative or on a petition from an interested person justifying such action.

REGULATIONS

Sec. 405. The Office of Federal Procurement Policy will direct the issuance of regulations specifying the terms and conditions upon which federally-owned patent rights may be licensed. An agency may deviate from such regulations on a class basis unless prohibited by the Office of Federal Procurement Policy.

TITLE V—MISCELLANEOUS

PATENT ENFORCEMENT SUITS AND RIGHT OF INTERVENTION

Sec. 501. Any exclusive licensee under this Act may enforce rights under the license by bringing suit without joining the United States as a party. However, the licensee will give prompt notice of the suit to the Attorney General and to the agency that granted the license, and all parties will serve copies of papers on the Attorney General and the responsible agency as though they were parties to the suit.

BACKGROUND RIGHTS

Sec. 502. Nothing contained in this Act will be construed to deprive the owner of any background patent of rights under such a patent.

NOTICE, HEARING, AND JUDICIAL REVIEW

Sec. 503. (a) Agency determinations under sections 201, 206(a), and 206(c), and 404 will be made after public notice and opportunity for a hearing in which the United States, any agency, or any interested person may participate, and will include written reasons for the determination.

(b) The United States or any participant that may be adversely affected by an agency determination covered by subsection (a) of this section may appeal the determination to the United States Court of Claims within sixty days after the determination is issued. That Court will have exclusive jurisdiction to determine the matter de novo and to affirm, reverse or modify the agency determination.

RELATIONSHIP TO OTHER LAWS

Sec. 504. Nothing in this Act creates any immunities or defenses to actions under the antitrust laws.

AUTHORITY OF FEDERAL AGENCIES

Sec. 505. (a) Agencies may apply for, obtain, maintain, and protect patent rights in the United States and in foreign countries on any invention in which the Government has an interest in order to promote the use of inventions having significant commercial potential or otherwise advance the national interest;

(b) Agencies may license federally-owned patent rights on terms and conditions consistent with Title V;

(c) Agencies may transfer patent rights to other agencies and accept them from other agencies, in whole or in part, without regard to the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 471);

(d) Agencies may withhold publication or release of information disclosing any invention long enough for patent applications to be filed;

(e) Agencies may promote licensing of federally-owned patent rights by making market surveys, acquiring technical information, or otherwise enhancing the marketability of the inventions; and

(f) Agencies may enter into contracts necessary and appropriate to accomplish the purposes of this section.

RESPONSIBILITIES OF THE SECRETARY OF COMMERCE

Sec. 506. (a) The Secretary of Commerce will—

(1) Consult with other agencies about areas of science and technology with potential for commercial development.

(2) Coordinate a program to help agencies in exercising the authority given by section 505;

(3) Evaluate intentions referred by agencies to identify those with the greatest commercial potential and to promote their agencies.

(4) Help agencies seek and maintain patents in the United States and in foreign countries by paying fees and costs and by other means;

(5) Develop and manage a Government-wide program, with appropriate private sector participation, to stimulate transfer to the private sector of potentially valuable federally-owned technology through dissemination of information about the technology; and

(6) Publish notice of all federally-owned patent rights that are available for licensing;

(b) There is authorized to be appropriated to the Secretary of Commerce such sums as may be necessary to enable the Secretary to carry out responsibilities under this section.

DEFINITIONS

Sec. 507. As used in this Act—

(1) "Agency" means an "executive agency" of the Federal Government, as defined by section 105 of title 5, United States Code, and the military departments defined by section 102 of title 5, United States Code. "Responsible agency" means the agency which is party to a contract for the performance of research or development, has received patent rights from another agency, or has administrative jurisdiction over an employee-inventor.

(2) "Antitrust laws" means the laws included within the definition of the term "Antitrust laws" in section 1 of the Clayton Act (15 U.S.C. 12), as amended, and the Federal Trade Commission Act (15 U.S.C. 41 et seq.), as amended.

(3) "Contract" means any Federal contract, cooperative agreement, or grant that provides for performance of research or development substantially funded by the Government. It covers any assignment, substitution of parties, or subcontract of the same type under such a contract. It does not cover Federal price or purchase supports, or Federal loans or loan guarantees.

(4) "Contractor" means any person other than an agency that is a party to a contract.

(5) "Federal employee" means any civil service employee as defined in section 2105 of title 5, United States Code, and any member of the uniformed services.

(6) "Invention" means any invention that is or may be patentable under the laws of the United States. "Contract invention" is defined by section 201. "Employee invention" is defined by section 301.

(7) "Made" when used in relation to any invention means conceived or actually reduced to practice.

(8) "Nonprofit organization" means universities and other institutions of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)).

(9) "Patent rights" means patents and patent licenses and sublicenses.

(10) "Practical application" means manufacture of a machine, composition, or product, or practice of a process or system, under conditions which establish that the invention is being worked and its benefits are available to the public on reasonable terms.

(11) "Small business" means a small business concern, as defined in section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration.

(12) "State" means a State or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. "Local" refers to any domestic county, municipality, or other governmental entity.

(13) "Will", except as the context otherwise requires, has the same meaning as "shall".

AMENDMENTS TO OTHER ACTS

Sec. 508. (a) Section 10(a) of the Act of June 29, 1935, as added by title 1 of the Act of August 14, 1946 (7 U.S.C. 427(a); 60 Stat. 1085) is amended by striking out the following: "Any contracts made pursuant to this authority shall contain requirements making the results of research and investigations available to the public through dedication, assignment to the Government, or such other means as the Secretary shall determine."

(b) Section 205(a) of the Act of August 14, 1946 (7 U.S.C. 1624(a); 60 Stat. 1090) is amended by striking out the following: "Any contract made pursuant to this section shall contain requirements making the result of such research and investigations available to the public by such means as the Secretary of Agriculture shall determine."

(c) Section 501(c) of the Federal Coal Mine Health and Safety Act of 1969 (30 U.S.C. 951(c); 83 Stat. 742) is amended by striking out the following: "No research, demonstrations, or experiments shall be carried out, contracted for, sponsored, cosponsored, or authorized under authority of this Act, unless all information, uses, products, processes, patents, and other developments resulting from such research, demonstration, or experiments will (with such exception and limitation, if any, as the Secretary or the Secretary of health, Education, and Welfare may find to be necessary in the public interest) be available to the general public."

(d) Section 106(c) of the National Traffic and Motor Vehicle Safety Act of 1966 (15 U.S.C. 1395(c); 80 Stat. 721) is repealed.

(e) Section 12 of the National Science Foundation Act of 1950 (42 U.S.C. 1871; 64 Stat. 149, 154) is repealed.

(f) Section 152 of the Atomic Energy Act of 1954 (42 U.S.C. 2182; 68 Stat. 943) is repealed.

(g) The National Aeronautics and Space Act of 1958 (72 Stat. 426) is amended—

(1) By repealing section 305 (42 U.S.C. 2457). However, subsections (c), (d), and (e) of section 305 shall continue to be effective with respect to any application for patents in which the written statement referred to in subsection (c) of such section has been filed or requested to be filed by the Commissioner of Patents and Trademarks before the effective date of this Act;

(2) By striking out, in section 306(a) (42 U.S.C. 2458(a)), "(as defined by section 305)"; and by striking out "the Inventions and Contributions Board, established under section 305 of this Act" and inserting instead: "an Inventions and Contributions Board which shall be established by the Administrator within the Administration";

(3) By inserting at the end of section 203(c) (42 U.S.C. 2478(c)) the following new paragraph:

"(14) To provide effective contractual provisions for reporting the results of the activities of the Administration, including full and complete technical reporting of any innovation made in the course of or under any contract of the Administration.";

(4) By inserting at the end of section 203 (42 U.S.C. 2478) the following new subsection,

"(d) For the purposes of chapter 17 of title 35 of the United States Code the Administration shall be considered a defense agency of the United States." and

(5) By striking out the following in such section:

"(Including patents and rights thereunder)".

(h) Section 6 of the Coal Research and Development Act of 1960 (30 U.S.C. 666; 74 Stat. 337) is repealed.

(j) Section 4 of the Helium Act Amendments of 1960 (50 U.S.C. 167b; 74 Stat. 920) is amended by striking out the following: "Provided, however, That all research contracted for, sponsored, cosponsored, or authorized under authority of this Act shall be provided for in such a manner that all information, uses, products, processes, patents, and other developments resulting from such research developed by Government expenditure will, with such exceptions and limitations, if any, as the Secretary may find to be necessary in the interest of national defense, be available to the general public: And provided further, That nothing contained herein shall be construed as to deprive the owner of any background patent relating thereto to such rights as he may have thereunder " and by inserting instead a period.

(k) Section 32 of the Arms Control and Disarmament Act of 1961 (22 U.S.C. 2572; 75 Stat. 634) is repealed.

(l) Subsection (e) of Section 302 of the Appalachian Regional Development Act of 1965 (40 U.S.C. App. 302(e); 79 Stat. 5) is repealed.

(m) Except for paragraph (1), section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 (42 U.S.C. 5901; 88 Stat. 1878) is repealed.

(n) Section 5(i) of the Tennessee Valley Authority Act of 1933 (16 U.S.C. 831d(i); 48 Stat. 61), is amended by striking both proviso clause at the end.

(o) Section 5(d) of the Consumer Product Safety Act (15 U.S.C. 2054(d); 88 Stat. 1211), is repealed.

(p) Section 3 of the Act of April 5, 1944 (30 U.S.C. 323, 58 Stat. 191), is repealed.

(q) The Resources Conservation and Recovery Act of 1976 (90 Stat. 2795) is amended—

(1) By repealing section 8001(c)(3) (42 U.S.C. 6981(c)(3); 90 Stat. 2831); and

(2) By striking out, in section 8004(c)(2) (42 U.S.C. 6984(c)(2)) the second sentence, notwithstanding section 6881(c)(3) of this title."

(r) Section 12 of the Electric and Hybrid Vehicle Research, Development, and Demonstration Act of 1976 (15 U.S.C. 2511;— Stat. —) is repealed.

(s) Paragraph (r) of Section 19 of the Federal Nonnuclear Energy Research and Development Act of 1974, Public Law 93-577, as amended, Public Law 95-238, is repealed; subparagraph (g) of said Section 19 is amended by striking "under section 9 of this Act" in the first sentence.

(t) Section 112(d)(2) of Public Law 95-39 enacted on June 3, 1977, is amended by striking "shall be governed by the provisions of Section 9 of the Federal Nonnuclear Energy Research and Development Act of 1974 and".

(u) Section 40a of the Water Research and Development Act of 1978 (42 U.S.C. 7572, 92 Stat. 1316) is repealed.

EFFECTIVE DATE

Sec. 509 This Act will take effect on the first day of the seventh month beginning after its enactment. Implementing regulations may be issued earlier.

SECTION-BY-SECTION ANALYSIS

TITLE I—POLICY

Sec. 101. Findings.

Section 101 states the finds of the Congress; namely, that:

"(1) Inventions that result from federally sponsored or supported research and development constitute a valuable national resource;

"(2) Federal policy on allocation of patent rights in such inventions should stimulate innovation, should meet the needs of the Government, should foster competition, should recognize the equities of Government contractors and Federal employee-inventors, and should provide small businesses and educational institutions with special incentives to participate in Federal research and development programs and to commercialize resulting inventions; and

"(3) The public interest would be advanced if greater efforts were made to promote commercial use of new technology that results from federally sponsored research and development."

Sec. 102. Purpose.

Section 102 states the purposes of this Act which are responsive to the directive Title I, Section 101(c) of P.L. 94-282, The National Science and Technology Policy, Organization and Priorities Act of 1976 that:

"Federal patent policies should be developed based on uniform principles, which have as their objective the preservation of incentives for technological innovation and the application or procedures which will continue to assure the full use of beneficial technology to serve the public."

The purposes of the Act are:

"(1) To establish an effective Federal system for management and use of inventions that result from federally sponsored or supported research and development.

"(2) To allocate patent rights in inventions that result from federally sponsored or supported research and development in ways that—

- A) Stimulate innovation,
 - B) Encourage participation of all qualified contractors,
 - C) Foster competition,
 - D) Reduce administrative burdens on Federal agencies and their contractors,
 - E) Promote widespread public use of inventions made with public support, and
 - F) Provide special incentives to small businesses and nonprofit organizations;
- "(3) To allocate equitably patent rights in Federal employee inventions;
- "(4) To provide for domestic and foreign patenting of federally-owned inventions and licensing of federally-owned patent rights, with the objective of strengthening the Nation's economy and expanding its domestic and foreign markets; and
- "(5) To amend or repeal inconsistent laws."

TITLE II—CONTRACT INVENTIONS

Sec. 201. "Contract Inventions"; Reporting.

Section 201 defines "contract inventions" and sets forth a contractor's responsibility with regard to a contract invention.

Subsection (a) defines "contract inventions" as "inventions made in the course of or under Federal contracts."

Subsection (b) requires that all contractors provide the responsible Federal agency with timely reports on each contract invention containing complete technical information about the invention and a list of each country, if any, in which the contractor elects to file a patent application. In addition, unless the contractor is a small business or nonprofit organization, contractors must list each field of use in which the contractor intends to commercialize the invention or otherwise achieve public use of the invention, e.g., by actively licensing it. Each selected field of use is to be described "with sufficient particularity to" distinguish those fields of use selected by the contractor from those fields of use left to the Government. The Government is prohibited from publishing or releasing these reports until the earlier of one year from receipt of all of the required information or the contractor has had a reasonable time to file a patent application; the Government may so withhold such information contained in other records or reports.

The field of use selection process intended to be undertaken unilaterally by the contractor without the need for negotiation with any Federal agency and only after an invention is made and reported to the Government. The standard of precision expected is that associated with normal business practice. The aim is for the contractor to indicate those fields of use in which it is interested commercially so that the Government can promote the commercialization of any unselected fields determined to be potentially valuable.

The temporary prohibition on publishing or releasing contractor reports is necessary in order to avoid the possible forfeiture of patent protection in some countries.

Subsection (c) provides for the responsible agency's depriving a contractor who fails to file the reports required by subsection (b) of any or all the rights it otherwise would have under Title II.

Sec. 202. Allocation of Rights—Small Business and Nonprofit Organizations.

Subsection (a) provides for the acquisition of title to contract inventions by contractors which are either a small business or a nonprofit organization. They would acquire title in each country listed under section (b)(2) of section 201 in which they filed a patent application within a reasonable time; their title would be subject to the Government's minimum rights under section 204 and to march-in rights under section 206.

Subsection (b) provides for acquisition of title to contract inventions by the Government in each country in which a small business or nonprofit organization elects not to file a patent application or fails to file within a reasonable time.

Sec. 203. Allocation of Rights—Other Contractors.

Subsection (a) provides for the acquisition of title by the Government to all contract inventions not made by a small business or nonprofit organization.

Subsection (b) provides for the contractor to receive an exclusive license in each field of use described under subsection (b) of section 201 in each country listed under that subsection in which it files a patent application within a reasonable time. The contractor's license is subject to the Government's minimum rights under section 205 and march-in rights under section 206.

Subsection (c) provides that the contractor will acquire its exclusive license by operation of law ninety days after providing the responsible agency with all the information required by subsection (b) of section 301 unless the agency earlier notifies the contractor of a determination under subsection (d) of this section with respect to any field of use. In that case, the contractor would acquire an exclusive license by operation of law in all other selected fields of use, if any.

Subsection (d) sets forth the basis for an agency determination that a contractor will not receive an exclusive license in a selected field of use.

The contractor will not acquire an exclusive license in any field of use if the responsible agency determines that the contractor's possession of such a license—

- (1) Would be contrary to the requirements of the agency's mission;
- (2) Would impair national security; or
- (3) Would violate the Federal antitrust laws if the receipt by the contractor of such a license were deemed an acquisition of assets of another corporation.

Subsection (d) is intended to be permissive. An agency is not required to undertake any determination, perhaps preferring to await actual experience under the exclusive license to see whether circumstances then justify exercise of a march-in right reserved by section 206. Further to reduce administrative burdens and to increase the security of the contractor in its knowledge that it will receive exclusive rights in the invention, the scope of the agency's inquiry underlying this determination is limited. The agency's review should focus on those unforeseen circumstances of which it has become aware since the time of contracting that now require it to deny the contractor an exclusive license in a particular field of use. The contractor should not be denied an exclusive license solely on the basis of facts that were known or reasonably foreseeable by the agency at the time of contracting. If such facts do exist at the time of contracting, the agency normally will deviate from the standard patent rights clause so that the contractor will know at that time that it will not receive an exclusive license to practice a forthcoming invention in a particular field of use.

Subsection (e) provides that, whenever an agency determines that a contractor will not receive an exclusive license in any field of use, it must include in its determination written reasons, and that the contractor has the right of appeal de novo to the United States Court of Claims within sixty days after the determination is issued. The Court of Claims is given exclusive jurisdiction to affirm, reverse, or modify the agency determination. Specifically included is the authority to order the responsible agency to issue an exclusive license to the contractor.

Subsection (f) permits the responsible agency to grant the contractor title to any contract invention in any foreign country in which the contractor agrees to file a patent application, provided the agency determines that the national interest would not be affected adversely.

Sec. 204. Contractor License.

Subsection 204 automatically grants a nonexclusive, royalty free license to each contractor complying with subsection (b) of section 201 to practice the contract invention in all countries in which it neither receives title under subsection (a) of section 202 nor receives an exclusive license under subsection (b) of section 203. This nonexclusive contractor license may be revoked by the Government only to the extent necessary to grant an exclusive license under Title IV. It is expected that, so long as the contractor is working the invention under its nonexclusive license, there would be no occasion to grant an exclusive license, and, therefore, no need to revoke the contractor's exclusive license.

Sec. 205. Minimum Government Rights.

Subsection (a) sets forth the minimum rights the Government has in every contract invention, unless waived under the authority of section 207. These minimum rights include:

- (1) The right to require from the contractor written reports on the use of the invention,
- (2) A royalty-free worldwide license to practice the invention or have it practiced for the Government, and
- (3) The right to license or sublicense State, local, or foreign governments to practice the invention or have it practiced for them, if the agency determines at the time of contracting that acquisition of this right would serve the national interest.

Subsection (b) requires that, whenever the Government has rights in a contract invention, notice of those rights are to be included in each patent application or patent on the invention.

Sec. 206. March-in Rights.

Section 206 sets forth the basis on which the responsible agency may terminate the contractor's title or exclusive rights with respect to one or more fields of use.

any patent on a contract invention; may require the contractor to grant appropriate license or sublicenses; or, if necessary, may grant such licenses or sublicenses itself.

Subsection (a) sets the grounds for exercise of the Government's march-in rights.

1) If the contractor has not taken and is not expected to take timely and effective action to achieve practical application of the invention in one or more of the fields of use selected;

2) If necessary to protect the national security;

3) If necessary to meet requirements for public use specified by Federal regulation;

4) If the contractor's rights in the invention would violate the Federal antitrust laws if the receipt by the contractor of those rights were deemed an acquisition of assets by another corporation; or

5) If the contractor has failed to comply with the reporting requirements of this Act.

The Government may march-in only in a field of use which gives rise to one or more of the situations described in the above five paragraphs. The fact that a contractor's behavior does not give rise to such a situation with respect to some field of use will not prevent the Government from marching-in in another field of use.

Subsection (b) permits the responsible agency to exercise its march-in rights either on its own initiative or in response to a petition from an interested person justifying such action. Agency failure to initiate a march-in proceeding in response to a petition is not a determination appealable to the United States Court of Claims under section 503.

Subsection (c) enables an agency to specify reasonable licensing terms whenever, in exercise of its march-in rights, it requires a contractor to grant, or itself grants, a license or sublicense.

Sec. 207. Deviation and Waiver.

Section 207 permits Federal agencies, to further an agency's mission or the public interest, to deviate from any standard patent rights clause issued under section 209, acquiring more or fewer rights to a contract invention.

Subsection (a) authorizes deviations either on a class basis in accordance with regulations to be issued under section 209, or, unless prohibited by those regulations, under regulations issued by an agency itself. Case-by-case deviations are permitted when authorized by the head of an agency or a designee, and described in the Federal Register.

Subsection (b) forbids waiver under any circumstances of the national security and antitrust march-in rights reserved by sections 206(a)(2), 206(a)(4), and 206(c) which provides for agency-set licensing terms in the event the Government requires licensing as a march-in remedy).

Subsection (c) forbids waiver of sections 203(a) [Government acquisition of title to contract inventions not made by small businesses or nonprofit organizations] and 206(a)(1) [Government march-in right for noncommercialization], except (1) in contracts involving a substantial contribution of resources by the contractor or (2) where a contractor whose participation is necessary to the successful accomplishment of an agency mission will not participate under the standard patent rights clause.

Sec. 208. Transfer of Rights to Contractor Employees.

Section 208 authorizes a contractor's employee-inventor to receive some or all of the contractor's rights to a contract invention if the responsible agency and the contractor approve. The corresponding obligations of the contractor under Title II then become the obligations of the employee.

Sec. 209. Regulations and Standard Patent Rights Clause.

Section 209 requires the Office of Federal Procurement Policy to direct the issuance of regulations implementing Title III, including the establishment of a standard patent rights clause or clauses.

TITLE III—INVENTIONS OF FEDERAL EMPLOYEES

Sec. 301. Employee Inventions.

Section 301 defines "employee inventions" as inventions made by Federal employees.

Sec. 302. Reporting of Inventions.

Section 302(a) requires that a Federal employee report to the employee's agency all inventions made while an employee of that agency. The Government is prohibited from publishing or releasing these reports until the earlier of one year after their receipt or the final disposition of rights under this Title.

Sec. 303. Criteria for the Allocation of Rights.

Section 303 establishes the criteria for allocation of invention rights between the Government and its employee-inventor. Basically, the allocation depends upon the relationship of the invention to the employee's work and the use of Government resources.

Paragraph (1) provides for Government acquisition of all invention rights if the invention bears a direct relation to the duties of the employee-inventor or was made in consequence of the employee's employment.

Paragraph (2) provides that, where the invention neither bears a direct relation to the employee's duties nor was made in consequence of the employee's employment, but was made with a contribution of Federal resources, the employee may receive all rights in the invention subject to a nonexclusive royalty-free worldwide license to the Government to practice the invention or have it practiced for the Government as well as to sublicense State, local, or foreign governments if acquisition of this right would serve the national interest.

Paragraph (3) permits the Government to waive to the employee its rights under paragraph (1) of this section, subject to the Government license described in paragraph (2) of this section.

Paragraph (4) requires the Government to acquire all rights in any invention if the national security might be impaired should the employee-inventor receive rights to it, notwithstanding the provisions of paragraphs (2) or (3) of this section.

Paragraph (5) entitles an employee-inventor to all rights in an invention made by the employee not covered by paragraphs (1), (2), or (3) of this section.

Paragraph (6) permits the Government to enter into agreements allocating rights in inventions resulting from research and development to which other parties have contributed substantially, notwithstanding paragraph (1) of this section.

Sec. 304. Presumptions.

Section 304 establishes rebuttable presumptions for the application of the criteria set forth in section 303.

Subsection (a) sets out employee duties which establish a rebuttable presumption that an invention falls within the criteria of paragraph (1) of section 303. Thus, for example, if an employee is assigned to conduct research and development work, it is presumed that the Government will have the right to title in any invention made.

Subsection (b) establishes a rebuttable presumption that an invention made by an employee whose duties fall outside those listed in paragraph (a) of this section falls within the criteria of paragraph (2) of section 303, reserving to the employee title to an employee-invention subject to certain license rights in the Government.

Sec. 305. Review of Agency Determinations.

Section 305 provides for the review of Federal agency determinations regarding the respective rights of the Government and a Federal employee-inventor in situations in which the agency determines not to acquire all rights in an invention to which an aggrieved employee-inventor requests review. The review is to be conducted according to regulations issued under section 309.

Sec. 306. Reassignment of Rights.

Section 306 establishes a right in the Government to adjust the rights acquired from a Federal employee-inventor on the basis of evidence that the granting of greater rights to the employee-inventor is necessary to correct an inequitable allocation of rights.

Sec. 307. Incentive Awards Program.

Subsection (a) provides Federal agencies the right to establish an incentive award program which is intended to monetarily recognize Federal employee-inventors, stimulate innovative creativeness, and encourage disclosures of inventions which in turn will enhance the possibility of utilization through the Federal licensing program established under Title IV.

Subsection (b) sets forth the criteria for making an award.

Subsections (c), (d), and (e) establish the procedures for making awards of different amounts.

Subsection (f) provides that acceptance of a cash reward constitutes an agreement by the employee-inventor that any use by the Government of an invention for which an award is made does not form the basis of a further claim of any nature against the Government by the recipient, his heirs, or assigns.

Subsection (g) requires that an award should be paid from the fund or appropriation of the agency primarily benefitting.

Sec. 308. Income Sharing from Patent Licenses.

Section 308 authorizes Federal agencies to share income from licensing the Government's patent rights with the employee-inventor.

Sec. 309. Regulations.

Subsection (a) makes the Secretary of Commerce responsible for issuing regulations to implement Title III.

Subsection (b) provides that determinations concerning a Federal employee's promotion of the employee's invention is subject to regulations to be prescribed by the Secretary of Commerce with the concurrence of the Office of Government Ethics and the Attorney General. The intention is to ensure that a Federal employee will not be prohibited from promoting his own invention if consistent with conflict of interests regulations.

TITLE IV—LICENSING OF FEDERALLY-OWNED INVENTIONS

Sec. 401. Covered Inventions.

Section 401 provides that Title IV applies to all federally-owned patent rights, including licenses or sublicenses granted or required to be granted by the Government under section 206. However it does not apply to licenses established by the other sections of Title II.

Sec. 402. Exclusive or Partially Exclusive Licenses.

Section 402 sets out terms and conditions under which a Federal agency may grant an exclusive or partially exclusive license.

Subsection (a) provides that an exclusive or partially exclusive domestic license may be granted only after public notice and opportunity for filing written objections and only if the responsible agency determines that such licensing is necessary to achieve practical application of the invention and that the scope of proposed exclusivity is not greater than reasonably necessary.

Subsection (b) provides that an exclusive or partially exclusive foreign license may be granted only after public notice and opportunity for filing written objections and after a determination whether the interests of the Government or of United States industry in foreign commerce will be enhanced.

Subsection (c) prohibits the granting of a license under this section if the responsible agency determines that the grant would violate the Federal antitrust laws if the receipt by the contractor of such a license were deemed an acquisition of assets of another corporation.

Subsection (d) requires Federal agencies to maintain publicly available, periodically updated records of their determinations to grant exclusive or partially exclusive licenses.

Sec. 403. Minimum Government Rights.

Section 403 sets forth the minimum rights the Government is to have in every exclusive or partially exclusive license. These minimum rights include:

"(1) The right to require from the licensee written reports on the use of the invention

"(2) A royalty-free, worldwide right to practice the invention or have it practiced for the Government, and

"(3) The right to license State, local, or foreign governments to practice the invention or have it practiced for them if the agency determines that reservation of this right would serve the national interest."

Sec. 404. March-in Rights.

Section 404 sets forth the basis on which the responsible agency may terminate an exclusive or partially exclusive license.

Subsection (a) sets forth the grounds for such termination:

"(1) If the licensee has not taken and is not expected to take timely and effective action to achieve practical application of the invention in the fields of use affected;

"(2) If necessary to protect national security;

"(3) If necessary to meet requirements for public use specified by Federal regulation;

"(4) If the licensee's rights in the invention would violate the Federal antitrust laws if the receipt by the contractor of those rights were deemed an acquisition of assets by another corporation; or

"(5) If the licensee has failed to comply with the terms of the license."

Subsection (b) permits the responsible agency to exercise its march-in rights either on its own initiative or in response to a petition from an interested person.

Sec. 405. Regulations.

Section 405 makes the Office of Federal Procurement Policy responsible for directing the issuance of regulations specifying the terms and conditions upon which federally-owned patent rights may be licensed. Agencies are permitted to deviate from such regulations on a class basis unless prohibited by the Office of Federal Procurement Policy.

TITLE V—MISCELLANEOUS

Sec. 501. Patent Enforcement Suits and Right of Intervention.

Section 501 provides for enforcement of an exclusive license under the Act by an exclusive licensee without the necessity of joining the United States as a party. The intention is to make the exclusive license the functional equivalent of title within the specified fields of use. However, the Attorney General and the agency that granted the license must be given prompt notice of the suit and served copies of papers as though they were parties to the suit.

Sec. 502. Background Rights.

Section 502 provides that nothing in the Act shall be construed to deprive the owner of any background patent or of rights under such a patent.

Sec. 503. Notice, Hearing, and Judicial Review.

Subsection (a) requires that agency determinations under sections 201 [failure to submit the reports required by subsection (b) of section 201], 206(a), and 206(c) [Government march-in rights], and 404 [Government march-in rights] must have written reasons and be preceded by public notice and an opportunity for a hearing in which the United States, any agency, and any interested person may participate.

Subsection (b) permits the United States or an adversely affected participant to appeal a subsection (a) determination to the United States Court of Claims within sixty days after it is issued. The Court of Claims is given exclusive jurisdiction to determine the matter *de novo*, affirming, reversing, or modifying the agency determination.

Sec. 504. Relationship to Other Laws.

Section 504 is intended to remove any implication that the Act provides immunity from the antitrust laws.

Sec. 505 Authority of Federal Agencies.

Subsections (a), (b), (c), (d), (e), and (f) set forth the authority of Federal agencies to protect patent rights at home and abroad in,

"Any invention in which the Government has an interest in order to promote the use of inventions having significant commercial potential or otherwise advance the national interest;"

To license federally-owned patent rights; to transfer patent rights to and accept transfers of patent rights from other agencies without regard to the property transfer procedures required by the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 471); to withhold publication or release of information disclosing any invention long enough for patent applications to be filed; to promote the licensing of federally-owned patent rights; and to enter into contracts to accomplish the purpose of this section.

Sec. 506. Responsibilities of the Secretary of Commerce.

Section 506 provides the authorities necessary for the Department of Commerce effectively to assist other Federal agencies administer the licensing of federally-owned inventions or to do so entirely by itself based on a transfer of patent rights to a federally-owned invention to the Department of Commerce pursuant to section 505(3).

Paragraph (a)(1) authorizes the Secretary of Commerce to coordinate a program, help agencies carry out their authorities under the Act.

Paragraph (a)(2) authorizes the Secretary to publish notices of all federally-owned patent rights available for licensing.

Paragraph (a)(3) authorizes the Secretary to evaluate inventions referred to it by Federal agencies in order to identify those inventions with the greatest commercial potential.

Paragraph (a)(4) authorizes the Secretary to develop and manage a government-wide program, with private sector participation, to stimulate transfer to the private sector of potentially valuable federally-owned technology.

Paragraph (a)(5) authorizes the Secretary to assist the Federal agencies in seeking and maintaining patent protection in any country, including the payment of fees and costs.

Paragraph (a)(6) authorizes the secretary to consult with the Federal agencies about areas of science and technology with commercial potential.

Subsection (b) authorizes the appropriation to the Secretary of Commerce of such sums as thereafter may be necessary to enable the Secretary to carry out responsibilities under this section.

Sec. 507. Definitions.

Section 507 sets out the definitions, for purposes of the Act, for the terms "Agency", "Responsible agency", "antitrust laws", "contract", "contractor", "Federal employee", "invention", "made", "nonprofit organization", "patent rights", "practical application", "small business", "state", "local", and "will".

Sec 508 Amendments to Other Acts

Section 508 is intended to amend or repeal parts of other acts covering similar subject matter. Acts which have been identified as covering similar subject matter are

- "Title 7, U.S.C. 427(j)"
- "Title 7, U.S.C. 1624(a)"
- "The Federal Coal Mine Health and Safety Act of 1969"
- "The National Traffic and Motor Vehicle Safety Act of 1966"
- "The National Science Foundation Act of 1950"
- "The Atomic Energy Act of 1954"
- "The National Aeronautics and Space Act of 1958"
- "The Coal Research and Development Act of 1960"
- "The Helium Act Amendments of 1960"
- "The Arms Control and Disarmament Act of 1961"
- "The Appalachian Regional Development Act of 1965"
- "The Federal Nonnuclear Energy Research and Development Act of 1974"
- "The Tennessee Valley Authority Act of 1933"
- "The Consumer Product Safety Act"
- "Title 30, U.S.C. 323"
- "The Resources Conservation and Recovery Act of 1976"
- "The Electric and Hybrid Vehicle Research, Development, and Demonstration Act of 1976"
- "Public Law 95-39"
- "The Water Research and Development Act of 1978"

Sec. 607 Effective Date

Section 607 provides that the Act shall take effect on the first day of the seventh month beginning after enactment. Implementing regulations may be issued earlier.

STATEMENT OF PURPOSE AND NEED

Government patent policy with respect to allocation of rights in patentable inventions resulting from federally sponsored or supported research and development bears a major responsibility for the pace of industrial innovation in the nation today as a result of the substantial amount of research and development work performed under contract with the government and by government employees.

Patents can serve several important functions in the innovation process. First, they provide the innovator with an incentive—a monopoly limited in time. Second, the exclusive rights provided by a patent can stimulate a firm to make the often risky investment that is required to bring an invention to market. Finally, a patent provides an important method for disclosure to the public of information about inventions and their uses.

In an October 31, 1979 Industrial Innovation Message to the Congress the President said:

"For over thirty years the Federal agencies supporting research and development in industry and universities have had conflicting policies governing the disposition of pertinent rights resulting from that work. This confusion has seriously inhibited the use of those patents in industry. To remove that confusion and encourage the use of those patents I will support uniform government patent legislation. That legislation will provide exclusive licenses to contractors in specific fields of use that they agree to commercialize and will permit the government to license firms in other fields. If the licensee fails to commercialize the invention, the government will retain the right to recapture those rights. I will also support the retention of patent ownership by small businesses and universities, the prime thrust of legislation now in Congress, in recognition of their special place in our society."

This bill contains the uniform government patent legislation the President announced. It is organized into three operative titles: Title II—Contract Inventions; Title III—Inventions of Federal Employees; and Title IV—Licensing of Federally-Owned Inventions.

CONTRACTOR INVENTIONS—TITLE II

Background

Since World War II, the Federal government increasingly has supported the overall research and development effort of the United States. At least initially, the patent policies of the Federal government generally were fashioned without any central guidance or coordination.

As the size of the Federal government's research and development effort increased, individual government agencies reacted differently to the problem of allocating rights to contractor-made inventions. Some agencies, notably the Department

of Defense, acquired a royalty-free license to contractor inventions and permitted the contractor to retain title, or what otherwise might be described as exclusive commercial rights. Other agencies financing research of interest to the private sector, such as the Department of Health, Education, and Welfare, decided to acquire all of the patent rights to inventions made by their contractors. Some agencies did not explicitly address the issue, thereby permitting their contractors to obtain all patent rights to inventions.

As the Congress became more concerned with rights in inventions made with government support, it enacted differing legislative policies for new research and development programs. In some instances the Congress provided guidance for the entire research and development effort of an agency, in others only for a specified program. Most often, the Congress required the Federal government to take title to all contract inventions.

The 1963 Presidential statement

As the issue developed prior to 1963, most participants in discussions of government patent policy advocated either that all patent rights be given to the government or that they all be given to the contractor (except for a royal-free, nonexclusive license for the government's own use). In 1963, President Kennedy issued a Statement on Government Patent Policy in an effort to achieve greater congruence in agency practices.¹ The policy applied to the research and development programs of all Federal agencies except where specific statutory requirements intervened. The large number of differing statutes made it impossible for the policy to achieve uniformity.

The 1963 Statement took the approach of classifying contracting situations into two categories: one in which the public interest presumptively would be served best by government acquisition of title; another in which title best would be acquired by the contractor. Recognizing that the Statement was based on a limited amount of information, exceptions were provided to the general rules and safeguards were established to protect the public interest against possible undesirable results.

An unsuccessful attempt at legislatively-mandated uniformity was made in 1965. Congressional hearings on the then proposed legislation resulted in a bill providing for a uniform policy substantially embodying the 1963 Statement. The bill was reported out of committee, but no further Congressional action was taken.

In late 1965, the Federal Council for Science and Technology (FCST) established the Committee on Government Patent Policy in order to assess how the 1963 Statement had worked in practice, to acquire and analyze additional information that would contribute to the reaffirmation or modification of the Statement, and to identify principles that should underline sound legislation in this area. The Committee, formed in response to Congressional pressure for an Administration position on uniform government patent policy legislation, provided a forum for senior policy-level officials to develop such a position.

The Committee supported what is perhaps the most extensive study ever conducted of the government patent policy issue. The results of this study, conducted by Harbridge House, Inc., of Boston, Massachusetts, are reported in four volumes.

Based upon its analysis of the Harbridge House study and operating experience under the 1963 Statement, the Committee concluded that, with minor revisions, the criteria specified in the Statement were satisfactory. Accordingly, in 1969 the Committee recommended that legislation, if proposed, should follow the basic criteria of the 1963 Statement. Alternatively, the Committee recommended modification of the 1963 Statement primarily directed toward increasing the flexibility of Federal agencies with regard to the allocation of patent rights and providing direction to the agencies with regard to the licensing of federally-owned inventions. In 1971 President Nixon issued a revised Statement on Government Patent Policy incorporating modifications recommended by the Committee.²

¹ Memorandum and Statement of Government Patent Policy Issued by President John Kennedy on October 10, 1963. (Published F.R., Vol. 28, No. 200, October 1963.)

² S. 1809. On April 23, 1965, Senator McClellan introduced in the 89th Congress, 1st Session, Bill "To Establish a Uniform National Policy Concerning Property Rights to Inventions and Through the Expenditure of Public Funds, and For Other Purposes." The Bill was amended and accepted by the Senate Judiciary Committee as the "Federal Inventions Act of 1966." (Not by full Senate.)

³ Government Patent Policy by Harbridge House, Inc., Boston, Mass., Volumes I-IV, May 1968. Superintendent of Documents, U.S. Printing Office, Washington, D.C. 20402—Contract 7-35087.

⁴ Memorandum and Statement on Government Patent Policy Issued by President Richard Nixon on August 23, 1971. (Published F.R., Vol. 66, No. 166, August 26, 1971.)

Commission on Government Procurement

In November of 1969, the Congress, by Public Law 91-129, established the Commission on Government Procurement to study and recommend methods "to promote the economy, efficiency and effectiveness" of procurement by the executive branch of the Federal government. Industry, trade and bar associations, individuals, members of the Executive Branch, and a full-time staff assigned to the Commission assisted it in the development of the Commission Report submitted to the Congress on December 31, 1971.¹ The bipartisan report contained 149 recommendations, six-teen of which related to patent, data, and copyright matters.

Recommendation No. 1 of Part I, Volume IV of the Report states:

Implement the revised Presidential Statement of Government Patent Policy promptly and uniformly."

Recommendation No. 2 states:

"Enact legislation to make clear the authority of all agencies to issue exclusive licenses under patents held by them."

Recommendation No. 1 was implemented in part by the issuance of the FPMR (licensing regulation) and the FPR (standard patent rights clause).² However, achievement of uniformity would have required the repeal of all conflicting statutory provisions. As with Recommendation 2, this would require legislation.

In September 1975, the FCST Committee on Government Patent Policy decided to prepare drafts of an Administration bill to implement these recommendations of the Commission's report. Legislation substantially based upon the Committee's work was introduced into the ninety-fifth Congress by Representative Thornton; hearings were held, but no further action was taken.

Domestic Policy Review of Industrial Innovation

Early in the Carter Administration, the Committee on Intellectual Property and Information (CIPI), the Federal Coordinating Committee for Science, Engineering, and Technology's successor to the Committee on Government Patent Policy, began working to develop an Administration position on government patent policy. Following the initiation of the President's Domestic Policy Review of Industrial Innovation in May of 1976, this effort was coordinated with the Domestic Policy Review.

As part of President Carter's Domestic Policy Review of Industrial Innovation, an assessment was made of the effect on such things as contractor participation in government research and development work and the commercial development of inventions made with government support of existing government policies with respect to the disposition of rights in patentable inventions made in the course of federally-supported research and development work. CIPI concluded that government ownership of inventions with the offer of unrestricted public use has resulted in almost no commercial application of federally-owned inventions. Without exclusive commercial rights, investors are unwilling to take the risks of developing a federally-generated invention and of creating a market for it. Thus, ironically, free public right to use a patent results, in practical terms, in a denial of the opportunity to use the invention. Second, many contractors, particularly those with strong background patents and experience, are unwilling to undertake work leading to freely available patents because this policy would compromise their proprietary position. Thus, some of the most capable performers will not undertake the government work for which they are best suited.

As a result of the strength of these considerations, most agencies have the authority, in at least some circumstances, to provide exclusive commercial rights to contractors. This issue, however, has been unsettled for a generation because of the difficulty of balancing competing considerations, and because various agencies operate under different and contradictory statutory guidance. The uncertainty and lack of uniformity in policy itself has had its negative effect upon the commercialization of technologies developed with Federal support. Title II of the present bill reflects the President's decision with respect to these issues.

INVENTIONS OF FEDERAL EMPLOYEES—TITLE III

In 1950, President Truman, in an attempt to bring about consistency in the allocation of rights to inventions made by Federal employees, issued Executive

¹ Volumes I-IV, Report of the Commission on Government Procurement, Superintendent of Documents, U.S. Printing Office, Washington, D.C. 20402. Stock Nos. 5255-00002; 5255-00003; 5255-00004; and 5255-00006.

² Amendment A-16 to Federal Property Management Regulations Issued January 29, 1973. (F.R., Vol. 38, No. 23, February 5, 1973.)

³ Amendment 116 to Federal Procurement Regulations issued August 29, 1973. (F.R., Vol. 38, No. 179, September 4, 1973.)

Order 10096.* Generally based on common law principles for allocating invention rights to employees in situation not covered by contract, this Executive Order applied to most, but not all, Federal employees. The order was held to be an unconstitutional encroachment on Congress' power in *Kaplan v. Johnson*, 409 F.2d Supp. 190 (N.D. Ill. 1976). This decision was reversed, however, by the court of appeals on the ground that Congress had authorized the promulgation of the Executive Order through its enactment of Sections 301, 3301, and 7301 of Title 5 of the United States Code. *Kaplan v. Corcoran*, 545 F.2d 1073 (7th Cir. 1976). The present bill codifies longstanding Federal practice in this area.

LICENSING OF FEDERALLY-OWNED INVENTIONS—TITLE IV

Federal Property Management Regulations (FPMR)

Section 2 of the 1971 Statement directed the Administrator of General Services to issue regulations for the comprehensive licensing of federally-owned inventions. In January 1973, the Administrator issued an amendment to the FPMR concerned with the licensing of federally-owned inventions.⁸

The validity of this regulation was challenged by a complaint filed in the United States District Court for the District of Columbia by Public Citizen, Inc., and others.⁹ The complaint alleged that the exclusive licensing of federally-owned patents constituted a disposal of property in violation of Article IV, Section 3, Clause 2 of the Constitution. The District Court found for the plaintiffs, directing the Administrator to take immediate steps to void the licensing regulations. This the Administrator did.¹⁰

On appeal by the government, the court of appeals held that the plaintiffs were without standing to sue, and reversed the judgment of district court.¹¹ The Administrator then reinstated the licensing regulations.¹² Since the court of appeals did not reach the merits of the plaintiffs' complaint, the legality of any exclusive license granted by a Federal agency under authority of this regulation remains untested.

Federal Procurement Regulations (FPR)

Following the issuance of the 1971 Statement, regulations providing for standard patent rights clauses for use by all Federal agencies were drafted and subsequently promulgated by the Administrator of General Services in August of 1973.¹³ The validity of these regulations also was challenged by Public Citizen, Inc., in the United States District Court for the District of Columbia.¹⁴ The complaint alleged that, whenever the government acquired less than title to an invention made under government contract, the government, in effect, was disposing of property in violation of Article IV, Section 3, Clause 2, of the Constitution. The Administrator cancelled the regulations pending the outcome of the lawsuit.

The district court dismissed the complaint, finding that the plaintiffs lacked standing to sue. The plaintiffs appealed, but the court of appeals affirmed the judgment of the district court.¹⁵ In May, 1975, the regulations were reissued.¹⁶ Again, however, no final judgment was had as to the merits of the complaint.

The present bill provides for a comprehensive scheme for the commercialization of federally-owned patent rights in the public interest.

DRAFT BILL

Following the President's Message to the Congress, a drafting committee of CIPD members from the Departments of Commerce, Energy, and Justice, the National Science Foundation, and the Office of Science and Technology Policy, met for a

* Executive Order 10096: "Providing for a Uniform Policy for the Government with Respect to Inventions Made by Government Employees and for the Administration of Such Policy," President Harry S. Truman, January 23, 1950 (3 CFR, 1949-1953 Comp., p. 292); as amended by Executive Order No. 10930: "Providing for the Abolishment of the Government Patents Board and Providing for the Performance of its Functions," President John F. Kennedy, March 22, 1961 (26 F.R. 2583, March 28, 1961).

⁸ See note 6, p. 33.

⁹ *Public Citizen, Inc. v. Sampson* (C.A. No. 781-73 U.S.D.C.D.C.).

¹⁰ FPMR Temp. Reg. A-10 to Federal Property Management Regulations Issued February 12, 1974 (F.R., Vol. 39, No. 34, February 19, 1974.).

¹¹ *Sampson v. Public Citizen, Inc.* (C.A. No. 74-1619 D.C. Cir.).

¹² Amendment A-10 to Federal Property Management Regulations Issued October 1, 1974 (F.R., Vol. 40, No. 199, October 14, 1975).

¹³ See note 7 above.

¹⁴ *Public Citizen, Inc. v. Sampson* (C.A. No. 74-303 U.S.D.C.D.C.).

¹⁵ *Public Citizen, Inc. v. Sampson* (C.A. No. 74-1849 D.C. Cir.).

¹⁶ Amendment 147 to Federal Procurement Regulations Issued May 1, 1975 (F.R., Vol. 40, No. 89, May 7, 1975).

period of several weeks to develop statutory language embodying the President's policy. Their draft twice was circulated for comment to other Federal agencies.

The present bill stems from the belief that inventions resulting from federally-supported research and development constitute a valuable national resource; that Federal policy with respect to the allocation of patent rights in such inventions should seek to stimulate innovation, promote contractor participation in government research and development work, foster competition, recognize the equities of government contractors and Federal employee-inventors, and provide small businesses and nonprofit organizations with special incentives.

This bill establishes a uniform policy regulating the allocation and use of invention rights that belong to the Government. It eliminates the piecemeal and often conflicting approach to this subject that has developed through a combined system of regulation by general Presidential guidance and specific program-by-program statutory direction. The bill amends or repeals all other Acts and supersedes all Presidential memoranda and Executive Orders concerning the allocation of invention rights resulting from federally sponsored or supported research and development and the licensing of federally-owned patent rights.

Title I states as the primary purpose of the bill the establishment of an effective Federal system for management and use of inventions that result from federally sponsored or supported research and development, based on the finding that such inventions constitute a valuable national resource which should be developed in a manner which stimulates innovation and recognizes the equities of Federal employees and contractors while safeguarding the public interest.

Title II of the bill allocates rights between contractors and the Government in inventions resulting from federal research and development contracts. When the contractor is a small business or a nonprofit organization, it may elect to acquire title in the invention in any country in which it files a patent application. Other contractors will receive exclusive licenses to practice contract inventions in whatever fields of use they choose to specify and agree to commercialize in whatever countries in which they file patent applications as long as their acquisition of such licenses would not conflict with the requirements of the agency's mission, the national security, or the Federal antitrust laws.

When the contractor receives title in or exclusive licenses to practice an invention, the Government will receive a nonexclusive, royalty-free, world-wide right or license to practice the invention or have it practiced for the Government. In addition, the Government will receive as to each invention the right to terminate the contractor's title or exclusive license, to require the contractor to grant appropriate licenses or sublicenses on reasonable terms to responsible applicants, or, if necessary, to grant such licenses itself. The Government may exercise this march-in right only if the contractor fails to commercialize the invention, if necessary to protect the national security, if necessary to meet requirements for public use specified by Federal regulations, if the contractor's rights in the invention would violate the antitrust laws were those rights deemed an acquisition of assets of another corporation, or if the contractor fails to comply with the reporting requirements imposed by the responsible agency.

The Office of Federal Procurement Policy is instructed to direct the issuance of regulations to implement Title II. The regulations will establish a standard patent rights clause allocating invention rights in accordance with the provisions of Title II. Generally, this clause will be included in Federal research and development contracts.

The contracting agency may deviate from the standard patent rights clause in furtherance of the agency's mission and the public interest. The agency may deviate on a class basis in accordance with the regulations issued under the direction of the Office of Federal Procurement Policy, and unless prohibited by those regulations, the agency also may deviate on a case basis pursuant to regulations that it issues itself. All other deviations must be authorized by the head of the agency or a designee on a case-by-case basis and must be described in the Federal Register.

Such a deviation may permit the Government to acquire lesser or greater rights in an invention than it normally would receive under Title II. The agency may not, however, waive the Government's right to terminate the contractor's title or exclusive license for antitrust or national security reasons.

Title III of the bill allocates rights between Federal employees and the Government in reported inventions made by Federal employees. If necessary to protect the national security, the Government will acquire all rights in an invention that was made with Federal support. In addition, the Government will acquire all rights in any invention that bears a direct relation to the duties of the employee-inventor or was made as a consequence of the employee's employment. The bill creates a

rebuttable presumption that the invention was made incidental to the employee's employment when the inventor was employed or assigned to invent, improve, or perfect any patentable material; conduct, supervise, or coordinate federally sponsored or supported research or development work; or act as a liaison among agencies or individuals engaged in such work. Although the Government may receive all rights in a particular invention, if the agency finds insufficient interest in the invention to justify exercising those rights, it may assign some or all of them to the employee-inventor. Such an assignment, however, will be subject to the Government's reserved nonexclusive, royalty-free, world-wide right to practice the invention or have it practiced for the Government.

In all other situations in which an invention was made with Federal support, the employee-inventor will receive all rights in the invention, subject to the Government's national security rights and the Government's nonexclusive, royalty-free, world-wide license to practice the invention or have it practiced for the Government.

The employee-inventor is entitled to all rights in any invention that was not made with Federal support.

Finally, although the Government may be entitled to receive all rights in an invention, an agency may enter into agreements providing for the appropriate allocation of rights in inventions that result from research or development to which other parties have contributed substantially.

Regulations issued by the Secretary of Commerce will provide for the review of agency determinations allocating rights in employee inventions whenever the agency determines not to acquire all rights in an invention or an aggrieved employee-inventor requests a review.

Title III also authorizes the establishment of a monetary incentive awards program for the purpose of stimulating the production and disclosure of employee inventions. An additional incentive provision in the bill authorizes agencies to share income received from any patent license with the employee-inventor.

Title IV provides the authorities and responsibilities in Federal agencies necessary to administer effectively a program or programs for the domestic and foreign licensing of federally-owned patent rights. Exclusive and partially exclusive licenses may be granted, but only after public notice and opportunity for filing written objections and only if the responsible agency determines such licensing is necessary to commercialize the invention. No license may be granted if the responsible agency determines that the granting of the license would create a situation violative of the antitrust laws.

Title V addresses a variety of housekeeping issues raised by other titles. It authorizes any exclusive licensee under the bill to enforce its rights by bringing suit without joining the United States as a party. The exclusive licensee, however, must notify the Attorney General and the agency that granted the license and serve the Government with copies of all papers as though it were a party to the suit.

Title V provides that the bill may not be construed so as to deprive an owner of its rights under any background patent.

Title V also provides that an agency may decide to terminate the title or exclusive license received by a person under Title II or IV only after public notice and opportunity for a hearing in which the United States, any agency, or any interested person may participate. The agency will issue the rationale for any such decision in writing.

The United States or any participant adversely affected by any agency decision requiring public notice and opportunity for a hearing may appeal the decision to the United States Court of Claims. The Court of Claims will have exclusive jurisdiction to determine the matter de novo and to affirm, reverse, or modify the agency determination.

Title V states that nothing in the bill creates any immunities or defenses to actions under the antitrust laws.

Title V also sets forth the authority of Federal agencies to obtain, patent, license, transfer, and accept federally-owned patent rights. It also provides the Secretary of Commerce with authority to assist other Federal agencies and to otherwise engage in efforts to stimulate the transfer to the private sector of potentially-valuable federally-owned technology.

Finally, Title V defines the various terms used in the bill, includes a list of the statutes that the bill either will repeal or amend, and provides for the effective date of the bill.

CONCLUSIONS

Enactment of this bill would stimulate the industrial innovation process by contributing to the more effective utilization of inventions made in the course of

government-supported research and development work. Further, the bill would resolve longstanding policy issues, answers to which the Congress, the Executive Branch, industry, and the public generally actively have sought for a generation. The bill is designed to reduce the administrative burden now imposed upon contractors and government agencies alike. Further, the bill responds to the Commission on Government Procurement recommendations, set forth in the bipartisan report to the Congress, that legislation be enacted which would make uniform the Federal practices in the area of allocating the rights of contract inventions and make clear the government's authority to grant exclusive licenses under federally-owned inventions. The bill also would codify the basic policy concepts of Executive Order 10096, the provisions of which uniformly would be applicable to all Federal employees. In addition, passage of this Bill would overcome any remaining legal questions raised by past litigation.

It is anticipated that, following implementation of the Act, greater commercial use will be made of the technology resulting from the Federal government's research and development effort, in turn creating additional employment, a higher standard of living, and an overall economic benefit to the United States as a whole, while protecting the public against any possible wrongful contractor conduct.

Senator STEVENSON. Thank you, sir.

Well, I would like to try to understand this approach a little better. I started with a strong preference for a conceptually cleaner, more far-reaching bill. You make distinctions for small businesses. Are they defined in the same way as in the Judiciary Committee bill? How small is small?

Dr. BARUCH. The bill uses the SBA definition, Senator Stevenson, which I think is 500 people.

Senator STEVENSON. That's implemented by regulation, is it not? In effect, it will be delegated to SBA to determine who gets what rights to Government-financed research?

Dr. BARUCH. That's an interesting point. If that concerns you, we can certainly put a more specific definition in the bill.

Senator STEVENSON. I don't know how much it concerns me at the moment. It's something that I don't feel very comfortable with, and I shouldn't think it would make businesses very comfortable.

Mr. HERZ. Senator Stevenson, I have doublechecked here. I believe that is essentially the same definition that is in the Bayh-Dole bill. It may be, however, that it would be better to have a more precise definition.

Senator SCHMITT. Or less precise.

Mr. HERZ. Possibly.

Senator STEVENSON. Another aspect of this that puzzles me: As soon as you pass the threshold, wherever it is, you get punished; you get punished by success. If a small company, as a result of its industry and its initiative, its innovation, becomes profitable, it gets punished, doesn't it?

Now, why shouldn't we be rewarding it instead of penalizing it for its success? Take Itek Corp., starting from nothing. As soon as it becomes what it is today, it doesn't qualify for the benefits accorded small business under your approach. What is the rationale for discriminating against success?

Dr. BARUCH. When you put it that way, Senator, we can never find a rationale for punishing success unless it's success at thievery or some other illegal act.

No; that's not the purpose. The purpose is not to punish success. Nor do we think it would be perceived as punishment by many of the companies, most of the companies. As the company gets larger, the limit of the span of business in which it can engage starts to be

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